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PART I

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Title 6—AGRICULTURAL CREDIT

Chapter III—Farmers Home Administration, Department of Agriculture

SUBCHAPTER B—LOANS AND GRANTS PRIMARILY FOR REAL ESTATE PURPOSES

[FHA Instruction 444.1]

PART 322—LOANS AND GRANTS PRIMARILY FOR REAL ESTATE PURPOSES

Subpart A—Section 502 Loan Policies, Procedures, and Authorizations

PART 386—DISPOSAL OF RESERVED MINERAL INTERESTS

Miscellaneous Amendments

Part 322, Title 6, Code of Federal Regulations (28 F.R. 13343) is entitled "Rural Housing Loans and Grants" and Part 386, Title 6, Code of Federal Regulations is superseded by Subpart A in Title 6, Code of Federal Regulations which reads as follows:

Sec.
322.1 General.
322.2 Objectives.
322.3 Definitions.
322.4 Eligibility requirements.
322.5 Veterans' preference.
322.6 Loan purposes.
322.7 Special requirements.
322.8 Rates and terms.
322.9 Technical service.
322.10 Security.
322.11 Processing applications and County Committee certification.
322.12 Preparation of loan docket.
322.13 Loan approval.
322.14 Actions subsequent to loan approval.
322.15 Subsequent section 502 loans.

AUTHORITY: The provisions of this Subpart A issued under sec. 510, 63 Stat. 437; 42 U.S.C. 1480; Orders of Sec. of Agr., 19 F.R. 74, 28 F.R. 9676, 29 F.R. 366, 2433. Additional authority is cited in parentheses following the sections affected.

§ 322.1 General.

This Subpart A prescribes the policies, procedures, and delegations of authority for making initial and subsequent Rural Housing loans under section 502 of the Housing Act of 1949 including the special authorizations in the Senior Citizens Housing Act of 1962. Additional provisions for making special types of Rural Housing loans are contained in Subchapter D of this chapter.

The basic objectives of the Farmers Home Administration in making section 502 loans are to assist farm owners, owners of other land in rural areas, and senior citizens who are or will be owners of land in rural areas to obtain decent, safe, and sanitary dwellings and related facilities, and to assist farm owners and owners of other land in rural areas obtain essential farm service buildings and related facilities. These loans give families who do not have sufficient resources to provide needed building improvements and cannot obtain credit from other sources on terms and conditions they reasonably can be expected to fulfill, an opportunity to have adequate homes and farm service buildings.

(Sec. 501, 63 Stat. 432, as amended; 42 U.S.C. 1471)

§ 322.3 Definitions.

For purposes of this subpart, the following definitions will apply:

(a) *Farm.* The term "farm" includes the total acreage of one or more tracts of land which is owned by the applicant; is operated as a single unit; is in agricultural production; and annually will produce agricultural commodities for sale and home use with a gross value of at least $400 based on 1944 prices. A building site in a town, village, or other place may be considered to be a part of a farm if the building site is so situated with respect to farm land owned and operated by the applicant that it is generally recognized as being a part of his farm and living off the farm is the general pattern in the community.

(b) *Nonfarm tract.* The term "nonfarm tract" means a parcel of land that is not a farm or part of a farm and is located in a rural area. The term "rural area" means open country or a small rural community. The term "small rural community" means a place of 2,500 persons or less that is not a part of, or associated with, an urban area. In determining whether an applicant's land is in a rural area, the following general rules will apply:

(1) If the latest population figures of any town, village, or other place, irrespective of whether it is incorporated or unincorporated, exceed 2,500, a loan may not be made within the prescribed limits of the place or in any densely settled areas near the place unless the land owned by the applicant qualifies as a farm, or a part of a farm including a building site as provided in paragraph (a) of this section.

(2) In determining whether a residential area is to be considered near or a part of a place of more than 2,500 people, minor open spaces due to physical barriers, commercial or industrial developments, parks, and areas reserved for convenience or appearance will be disregarded.

(3) Loans will not be made in established communities or in subdivision developments near or primarily associated with an urban area.

(4) Loans will not be made in a substantial-size subdivision being developed in a rural area unless a large proportion of the residents will obtain most of their income from employment in the surrounding rural area.

(c) *Owner.* The term "owner" includes the following in addition to the ordinary owner in fee simple:

(1) A lessee holding a leasehold interest in a farm in a case where the unexpired term of the lease runs beyond the payment period of the loan and the applicant's equity in his leasehold interest is at least equal to the amount of the loan; where there is a reasonable probability of accomplishing the objectives for which the loan is made; when the applicant can give upon his leasehold interest a recorded mortgage constituting a valid and enforceable lien; the applicant can comply with loan security requirements specified in this Subpart A; and where the unexpired term of the lease runs for at least 10 years. This does not include a lessee of a nonfarm tract.

(2) The owner of an undivided interest in land who is otherwise eligible.

(3) The purchaser under a purchase contract which obligates him to pay the purchase price, gives him the rights of possession, control, and beneficial use of the property, and entitles him to a deed upon paying all or a specified part of the purchase price.

(4) The holder of a life estate having the usual rights of possession, control, and beneficial use of the property. A remainderman is not an owner but will be required to join in executing the mortgage where a mortgage on the farm is required as security and may be required to join in signing the note if necessary for a sound loan.

(d) *Mortgage.* The term "mortgage" includes any form of security interest or lien upon any rights or interest in property of any kind.

(e) *Security.* The term "security" includes any rights or interests in property of any kind subject to a mortgage.

(f) *Real estate.* The term "real estate" includes the rights and interests of an owner, as defined in paragraph (c) of this section in a farm or nonfarm tract.

(g) *Senior citizen.* The term "senior citizen" means a citizen of the United States who is 62 years of age or over and resides in a rural area.

(h) *Senior citizen loan.* The term "senior citizen loan" means a section 502 Rural Housing loan to a senior citizen.

(i) *Cosigner.* The term "cosigner" means a comaker who is jointly and severally liable with the borrower.

(Secs. 501, 502, 63 Stat. 432, as amended, 433, as amended; 42 U.S.C. 1471, 1472)

§ 322.4 Eligibility requirements.

(a) *Applicant.* To be eligible for a section 502 loan, the applicant must:

(1) Be the owner of a farm or nonfarm tract or a senior citizen who is such an owner or will, when the loan is closed, become the owner of a minimum adequate building site.

(i) If he applies as the owner of a farm, it must be without decent, safe, and sanitary housing for his own use or for the farm manager, tenants, sharecroppers, or farm laborers, or without

farm service buildings essential to a successful farming operation.

(ii) If he applies as the owner of a nonfarm tract, he must be without decent, safe, and sanitary housing for his own use, or if he is engaged in farming be without farm service buildings essential to the success of his farming operations.

(iii) If he applies as a senior citizen, he must be a rural resident who is without an adequate dwelling or related facilities for his own use. To qualify as a rural resident he must either be living in a rural area at the time he applies for a loan or have recently lived in a rural area.

(2) Be without sufficient resources to provide on his own account the necessary housing, buildings, or repair and improvements thereto, and be unable to secure the necessary credit from other sources upon terms and conditions which he reasonably could be expected to fulfill.

If the applicant has an undivided interest in the land to be improved, the applicant and his co-owners, individually and jointly, must, except as provided in § 322.7(j), be unable to provide the improvements with their own resources or obtain the necessary credit elsewhere.

(3) Be a citizen of the United States.

(4) Have income sufficient to meet his operating and family living expenses, necessary capital replacements, and payments on debts, including the proposed loan, except that if he is a senior citizen whose income is not sufficient for repayment of the loan, he may qualify for a loan if a person or persons with income, which, when added to the applicant's income will be sufficient to pay the loan, will become a co-signer.

(5) Possess the character, ability, and experience to carry out the undertakings and obligations required of him in connection with the loan.

(6) Have training or farming experience necessary to give reasonable assurance of success whenever the soundness of the loan depends on the farming operations.

(7) Possess legal capacity to incur the obligations of the loan.

(Secs. 501, 502, 63 Stat. 432, as amended, 433, as amended; 42 U.S.C. 1471, 1472)

§ 322.5 Veterans' preference.

The applications on hand from veterans, and from spouses of children of deceased servicemen, as defined in § 301.5 of this chapter, will be given preference.

(Sec. 507, 63 Stat. 436, as amended; 42 U.S.C. 1477)

§ 322.6 Loan purposes.

Loans may be made for:

(a) *Loans to other than senior citizens*—(1) *Dwellings and farm service buildings.* (i) If the real estate to be improved is a farm, a loan may be made to construct, improve, or relocate on the farm a dwelling needed for the use of the farm owner, manager, tenants, sharecroppers, or farm laborers, or farm service buildings essential to the success of the farming operation.

(ii) If the real estate to be improved is a nonfarm tract, a loan may be made to construct, improve, or relocate on the applicant's land a dwelling and related facilities to be used by the applicant as his permanent residence and if he is engaged in farming, buildings essential to the success of the applicant's farming operation.

(iii) To purchase and transfer to the applicant's land a dwelling or other building.

(iv) To provide fallout shelters, storm cellars, or similar protective structures.

(v) To provide or improve sewage disposal systems.

(vi) To purchase and install essential equipment which upon installation becomes a part of the real estate.

(vii) To provide portable-type farm service buildings that do not become part of the real estate, if the buildings are necessary for the successful operation of the farm.

(viii) To provide foundation plantings, seeding or sodding of lawns, and other facilities related to buildings, such as walks, paved feed lots, yard fences, and driveways to building sites located adjacent to a road or street.

(2) *Water supply.* To provide water supply for dwellings and farm buildings, including such facilities as wells, pumps, and farmstead distribution systems, which are essential to the health and safety of the family or necessary to the successful operation of a livestock enterprise.

(3) *Miscellaneous fees and expenses.* To pay expenses incident to obtaining plans and making the loan, such as fees for legal, architectural, and other technical services, and reasonable connection fees for water, sewerage, electricity, or gas, which are required to be paid by the borrower and which he cannot pay from other funds. Loan funds also may be used to pay the borrower's share of Social Security taxes for labor hired by the borrower in connection with making the planned building improvements. Loan funds may not be used to pay fees, charges, or commissions, such as "finders' fees" or "placement fees," for the referral of prospective applicants to the Farmers Home Administration.

(b) *Loans to senior citizens.* A senior citizen loan may be made for the purposes authorized in pargaraph (a) of this section, except those for dwellings and related facilities not to be used by the applicant or for farm service buildings and related facilities. In addition, a senior citizen loan may be made to buy a previously occupied dwelling and land constituting a minimum adequate site, or to buy a minimum adequate site and construct a dwelling thereon. Such a minimum adequate site will not be larger than the smallest area sufficient for the dwelling and related facilities to be built, improved, or purchased, a yard, and land enough to produce food for home use only. A dwelling and related facilities financed with a senior citizens loan must be for the applicant's use as a permanent residence.

(Sec. 501, 63 Stat. 432, as amended; 42 U.S.C. 1471)

§ 322.7 Special requirements.

(a) *Supervisory assistance.* Supervision will be provided borrowers to the extent necessary to achieve the objective of the loan and to protect the interests of the Government in accordance with Part 302 of this Chapter.

(b) *Supplementary payment agreement.* Form FHA 440–9, "Supplementary Payment Agreement," should be used for each applicant who regularly receives substantial off-farm income. It also should be used for other applicants when needed to facilitate servicing the account.

(c) *Building limitations.* Section 502 loans will not be made to provide:

(1) Dwellings which are larger or more expensive than necessary to provide adequate though modest housing accommodations. Adequate housing ordinarily can be provided for families within about 1400 square feet of living area unless the family is unusually large. Living area does not include space such as a patio, carport, garage, porch not suitable for year-round use, unfinished basement, and, if the dwelling does not have a basement, space for utilities such as furnace and hot water heater. When an applicant has an unusually large family, a somewhat larger house which will provide adequate sleeping space may be justified. Furthermore, particular design features or items should not be financed with Rural Housing funds if such features or items are customarily not included in other adequate but modest homes being built in the area by families with moderate income.

(2) Farm service buildings which are excessive in size or design, have not proved to be suitable for the area, or are in excess of those economically essential to the farming operations.

(d) *Limitation on the use of funds for loans to senior citizens.* No loan funds may be included in a senior citizen loan for farm service buildings or for any income-producing land or buildings.

(e) *Refinancing of Rural Housing loan.* If, at any time, it appears that the borrower may be able to obtain a loan from a cooperative or private credit source at reasonable rates and terms for loans for similar purposes and periods of time prevailing in the area, to refinance his loan, the borrower will, upon request, apply for and accept such financing.

(f) *Loan limitations.* No loan will be made if the amount of the loan and the unpaid principal balance plus past-due interest of any other liens against the security as determined by the loan approval official will exceed the normal value of the security as determined by the loan approval official, or the loan exceeds the amount of loan certified by the County Committee.

(g) *Liens junior to the Farmers Home Administration lien.* A loan will not be made if a lien junior to the Rural Housing mortgage likely will be taken simultaneously with or immediately subsequent to closing of the loan to secure any debts the borrower may have at the time of loan closing, or any indebtedness he may incur in connection with the Rural Housing loan such as for a portion of the purchase price of the land or for money borrowed from others for payments on debts against the property, un-

less such a lien plus the Rural Housing loan and any prior lien will be within the normal value of the security.

(h) *Restrictions on loans.* Loans will not be made to:

(1) A corporation or cooperative association.

(2) A homestead entryman or desert entryman to improve the entry prior to receipt of a patent.

(3) Pay debts incurred prior to the closing of a loan except fees for legal, architectural, and other technical services. The County Supervisor, not later than the time of planning farm improvements, will advise each applicant that construction work must not be started and debts for such work or materials must not be incurred before the loan is closed. If, nevertheless, the applicant incurs debts for materials or construction before the loan is closed, the County Supervisor, or the Assistant County Supervisor in connection with loans for which he had delegated authority to approve, may authorize the use of Rural Housing funds to pay such debts only when, after documenting the facts, he finds that all of the following conditions exist:

(i) The debts were incurred after the applicant filed a written application for a loan, except that in the case of a subsequent loan to complete improvements previously planned, the debts were incurred after the initial loan was closed.

(ii) The applicant is unable to pay such debts from his own resources or to obtain credit from other sources and failure to authorize the use of Rural Housing funds to pay such debts would impair the applicant's financial position.

(iii) The debts were incurred for authorized section 502 loan purposes.

(iv) The construction or repair work conforms to that shown on Form FHA 424–1, "Development Plan."

(4) An applicant whose debts have been settled pursuant to Part 364 of this chapter, or who has been released from personal liability under Part 372 of this chapter, as reflected by the County Office records, or where such settlement is contemplated, unless the applicant's failure to pay his loan indebtedness was the result of circumstances beyond his control; the conditions which necessitated the debt settlement, other than weather hazards, disasters, or price fluctuations, have been or will be removed by making the loan; and the borrower's operations will be sound and afford him a reasonable prospect for repaying the loan and meeting his other obligations.

(i) *Loans on leasehold interests in farms.* A loan secured by a mortgage upon a leasehold, if otherwise proper and in accordance with state law, may be made where the lessor owns the fee simple title marketable in fact and neither the leasehold nor the fee title is subject to a prior lien. If in any case involving a prior lien the State Director concludes that a sound loan can be made upon a leasehold, he will submit complete information to the National Office for review and special authorization prior to approval of the loan. Loans may not be made to lessees of nonfarm tracts. With respect to achieving the purpose of the loan, obtaining adequate security, and being able to service the loan and enforce the security, the Government as holder of a mortgage upon a lease or leasehold interest must be in a position substantially as good as if it held a second mortgage on a fee simple title. This includes besides lessor's consent to the Rural Housing mortgage, such matters as:

(1) Reasonable security of tenure. The borrower's interest will not be subject to summary forfeiture or cancellation.

(2) The right to foreclose the Rural Housing mortgage and sell without restrictions that would adversely affect the salability or market value of the security.

(3) Right of Farmers Home Administration to bid at foreclosure sale or to accept voluntary conveyance of the security in lieu of foreclosure.

(4) The right of Farmers Home Administration, after acquiring the leasehold through foreclosure or voluntary conveyance in lieu of foreclosure, or in event of abandonment by the borrower, to occupy the property or sublet it, and to sell for cash or credit. In case of a credit sale, the Farmers Home Administration will take a vendor's mortgage with rights similar to those under the original Rural Housing mortgage.

(5) The right of the borrower, in the event of default or inability to continue with the lease and the Rural Housing loan, to transfer the leasehold, subject to the Rural Housing mortgage, to an eligible transferee with assumption of the Rural Housing debt.

(6) Advance notice to Farmers Home Administration of lessor's intention to cancel, terminate, or foreclose upon the lease. Such advance notice will be long enough to permit Farmers Home Administration to ascertain the amount of delinquencies, the total amount of the lessor's and any other prior interest, and the market value of the leasehold interest and, if litigation is involved, to refer the case with a report of the facts to the United States Attorney and permit him to take appropriate action.

(7) Express provisions covering the question of liability of Farmers Home Administration for unpaid rentals or other charges accrued at the time it acquires possession of the property or title to the leasehold, and those which become due during Farmers Home Administration's occupancy or ownership, pending further servicing or liquidation.

(8) Any necessary provisions to assure fair compensation for any part of the premises taken by condemnation.

(9) Any other provisions necessary to meet the requiremets of paragraph (i) of this section.

(j) *Group service participation loans.* A Section 502 loan may be made to an eligible farm owner to enable him to furnish his part of the cost of constructing, remodeling, or repairing a farm service building, such as a dairy barn, storage facility, or housing for farm labor, that will be jointly owned and used by not more than 10 farmers. The following conditions must be met before such a loan can be approved.

(1) The group of farmers must act as individuals and not as a legal entity such as a partnership, corporation, or association.

(2) The building will be located in a rural area and provide an essential farm service facility to be used only in connection with the farming operations which the owners of the building conduct on other land.

(3) When real estate security is required, the applicant will give the Farmers Home Administration a mortgage on his farm including his undivided interest in the tract to be improved with the loan. Other co-owners who are not applicants will not be required to mortgage their interests.

(4) The owners have written agreements as to the construction and use of the service building.

(5) The service buildings will not cost more than $50,000 if new buildings are being constructed or have a depreciated replacement value as improved of more than $50,000 if existing buildings are being enlarged or improved.

(6) All of the funds to be used to finance the joint facility will be deposited in the supervised bank account.

(k) *Section 502 loans to Farm Ownership or Soil and Water borrowers.* (1) When a Farm Ownership or Soil and Water borrower's total subsequent credit needs can be met with a Section 502 loan, such a loan may be made if:

(i) The borrower meets the eligibility requirements for a Section 502 loan and a Farm Ownership loan or Soil and Water loan. However, in an exceptional case a Rural Housing loan may be made to a Farm Ownership borrower who, because of age, physical disability, or death of the spouse, is unable to operate the farm or carry on farming operations large enough to qualify as a family farm, provided a decision has been made to continue with the Farm Ownership loan.

(ii) The loan, when added to the unpaid principal balance plus past-due interest of any Farm Ownership, Soil and Water, Rural Housing, or Labor Housing loan plus other debts against the farm or any other security given for a Farmers Home Administration real estate loan or to be given for the section 502 loan, will not exceed $60,000, or the normal value of the security for the loan, whichever is less.

(2) A loan may be made to a Farm Ownership or Soil and Water borrower on the basis of real estate security, nonreal estate security, or a note only.

(3) If the farm will be taken as security, a new appraisal will be prepared when the circumstances outlined in § 322.15(a) exist.

§ 322.8 Rates and terms.

(a) *Interest rate.* The interest rate on loans will be 4 percent per year on the unpaid principal.

(b) *Amortization period.* Each loan will be scheduled for repayment over a period not to exceed 33 years from the date of the note or such shorter period as may be necessary to assure that the loan will be adequately secured, taking into account the probable depreciation of the security, except that a loan not se-

cured by a real estate mortgage will be scheduled for repayment over a period not to exceed 10 years from the date of the note.

(Sec. 502, 63 Stat. 433, as amended; 42 U.S.C. 1472)

§ 322.9 Technical service.

(a) *Planning and performing development.* The development work will be planned and completed in accordance with Part 304 of this chapter.

(b) *Appraisal.* (1) For a loan exceeding $2,500, the real estate to be improved and given as security will be appraised by a Farmers Home Administration employee authorized to make real estate appraisals. If a mortgage will be taken on other real estate as additional security, it will be appraised when it represents a substantial portion of the security for the loan or when requested by the County Supervisor or other loan approval official.

(2) For a loan not exceeding $2,500, an appraisal of real estate to be given as security will not be made unless the County Supervisor or loan approval official is uncertain as to the adequacy of the security. If, in such a case, an appraisal is not made by an employee authorized to make real estate appraisals, the County Supervisor will indicate on a separate sheet his estimate of the normal value of the real estate to be given as security.

(3) For security other than real estate, the County Supervisor will list on Form FHA 440–21, "Appraisal of Chattel Property," or State form, if one has been developed, the items to be given as security and his estimate of the normal value of the security. In determining the value of chattel security (except a chattel mortgage on a leasehold), the County Supervisor will take into consideration the length of time the chattels will serve as security and the useful life of such security. In the case of other security, the County Supervisor will include in the appraisal form a supporting statement of his estimated value. Usually this will include a narrative description of the security, its current cash value, the relative stability of the security, and how the security is to be mortgaged or otherwise taken as security for the loan.

(4) In any case of a loan to a farm lessee not secured by a mortgage on the leasehold, the County Supervisor will indicate on a separate sheet his estimate of the normal value of the applicant's equity in his leasehold interest.

(c) *Title clearance and legal services.* (1) When real estate is taken as security (including a chattel mortgage on a farm leasehold), title clearance and legal services for making and closing the loan will be provided in accordance with Part 307 of this chapter. In such a case the applicant will be requested to furnish such title clearance at any time during the loan processing period when the County Supervisor determines that the loan probably will be made. If the County Supervisor is doubtful whether the loan will be approved, he will not require the applicant to furnish title evidence until after loan approval.

(2) When Part 307 of this chapter is not applicable, as provided in paragraph (c) of this section, the applicant will be required to submit the original or a certified or photostatic copy of his deed, purchase contract, or other instrument evidencing ownership. Whenever the County Supervisor is uncertain as to whether or not the applicant is a qualified owner, the County Supervisor will take such actions as he considers necessary, such as requiring the applicant to furnish additional information or obtaining the opinion of the Office of the General Counsel as to the evidence of ownership submitted by the applicant and his advice as to any further information or action that may be needed.

(3) When chattels are taken as security (except a chattel mortgage on a leasehold), a lien search will be obtained in accordance with Subpart B, Part 331 of this chapter.

(Secs. 506, 509, 63 Stat. 435, as amended, 436; 42 U.S.C. 1476, 1479)

§ 322.10 Security.

(a) *General.* Each loan will be adequately secured to protect the interest of the Government during the payment period of the loan.

(1) Any loan of more than $2,500 and any loan to be paid in more than 10 years from the date of the note will be secured by a mortgage on the farm or nonfarm tract to be improved unless an exception is made in accordance with paragraph (b)(1) of this section. Usually loans of more than $2,500 will be secured only by real estate. When necessary to supplement the applicant's equity in the property to be improved or to facilitate servicing the loan, a mortgage also may be taken on other real estate or on chattels or other property owned by the applicant. However, nonreal estate security may not be relied upon for more than $2,500 of the loan.

(2) A loan of not more than $2,500 to be paid in not more than 10 years from the date of the note may be secured by:

(i) Either real estate or chattels; or

(ii) Other security that cannot be converted to cash without jeopardizing the borrower's farming operations or means of livelihood;

(iii) The borrower's promissory note when the loan does not exceed $1,500.

(3) Whenever both real estate and chattel security are taken for a loan and the payment period of the loan will exceed the maximum period for which the chattel lien may be valid under State law, the loan approval official will determine whether the real estate security will be adequate to secure the scheduled unpaid balance of the loan when the chattel lien expires.

(b) *Real estate.* (1) When the loan is to be secured by real estate, a mortgage will be obtained on the entire farm owned by the applicant or on the nonfarm tract, except as provided in this paragraph. If the applicant's title to any part of the real estate is defective (either in the sense that it is not good title marketable in fact or that the State law will not recognize a mortgage upon it or will not permit such a mortgage to be recorded) and cannot be cured at reasonable cost, the loan may nevertheless be made if the value of the part of the applicant's property to which title is not defective and the value of necessary and available additional security are adequate to secure the loan, and if any improvements to be made with loan funds will be located on the part of the farm to which title is not defective, except that up to $2,500 in loan funds may be used for improvements on a part of the property owned by the applicant to which title is defective. Any part of the real estate to which title is defective may be omitted from the mortgage if the loan approval official with the advice of the Office of the General Counsel determines that the applicant's interest is of such a nature that it is not mortgageable or that to include it would unduly complicate loan servicing or liquidation.

(2) A junior mortgage may be taken as security for a loan, provided:

(i) Neither the prior mortgages nor the State law contains such future advance provisions, payment schedules, provisions for summary forfeiture or cancellation, or other provisions as may jeopardize the Government's security position or the borrower's ability to pay the loan; or

(ii) Such provisions are satisfactorily limited, modified, waived, or subordinated.

(3) When a mortgage on the farm is required in case of a borrower owning a leasehold interest, the borrower will give a valid and enforceable mortgage on his leasehold interest in the farm. The unexpired term of the lease must be at least 10 years and must extend beyond the repayment period of the loan for a sufficient period to provide a reasonable likelihood that the objectives of the loan will be achieved. The unexpired term of the lease must be at least 50 percent longer than the repayment period of the loan unless, to compensate for a shorter period of the lease beyond the repayment period of the loan, the borrower gives other security of sufficient value or the lessor agrees to compensate the borrower at the expiration of the lease for the unexhausted value of the improvements made with the loan. The mortgage on a leasehold may be supplemented by additional security. Special provisions necessary to protect the Government, will be included in the lease, a consent to mortgage, or other appropriate instrument.

(4) Except as provided in § 322.7(j), when the applicant is the owner of an undivided interest qualified under § 322.3, all his co-owners will be required to join in executing the real estate mortgage with the following additional exception: When one or more of the co-owners is not legally competent or cannot be located or the ownership rights are divided among such a large number of co-owners that it is not practical to obtain the signatures of all co-owners, execution of the mortgage by one or more of the owners may be waived with the prior consent of the National Office, provided the nonmortgaged interest is not more than 50 percent. In such a case the total debts against the security

may not exceed the pro rata portion of the value represented by the interests of the owners who sign the mortgage. Co-owners will be required to sign the note when necessary to a sound loan or to obtain the required security.

(5) When the applicant is the owner of a qualified life estate, the remaindermen will be required to join in executing the mortgage with the following exception: When one or more of the remaindermen is not legally competent or cannot be located or the remainder rights are divided among such a large number of remaindermen that it is not practicable to obtain the signatures of all remaindermen, execution of the mortgage by one or more of the remaindermen may be waived with the prior consent of the National Office, provided the nonmortgaged interest is not more than 50 percent of the total remainder interest. In such a case the total debts against the security may not exceed the pro rata portion of the value represented by the interests of the persons who sign the mortgage. Remaindermen will be required to sign the note when necessary to a sound loan or to obtain the required security.

(c) *Chattel.* When authorized by paragraph (a) of this section, a mortgage may be taken on selected items of chattel or other nonreal estate security if such a mortgage will not interfere with the applicant's obtaining needed operating credit. When only a chattel mortgage is taken as security for the loan, it ordinarily will be a first lien. In an exceptional case, a mortgage subject only to a first mortgage held by another creditor or the Farmers Home Administration may be taken on chattel property provided the applicant clearly has sufficient mortgageable equity in the chattels to secure the loan.

(d) *Promissory note.* A loan of not more than $1,500 may be made on the basis of the borrower's promissory note without taking other security when:

(1) The applicant has a good reputation for paying his debts promptly;

(2) He clearly will have sufficient income to meet all of his obligations; and

(3) The loan approval official determines that, on the basis of normal value, the applicant has equity at least equal to the amount of the proposed loan in assets that would be acceptable as security for the loan.

(Sec. 502, 63 Stat. 433, as amended; 42 U.S.C. 1472).

§ 322.11 Processing applications and County Committee certification.

(a) *Applications.* Applications for section 502 loans will be taken on Form FHA 410–1, "Application for FHA Services," and processed in accordance with Part 301 of this chapter. Before processing the application of an applicant other than a senior citizen who appears to be eligible for a loan, the County Supervisor should determine that the applicant is the owner of a farm or nonfarm tract.

(b) *Optioning of land.* If a senior citizen loan includes funds to purchase real estate, the applicable provisions of §§ 321.15 and 321.20 of Part 321 of this chapter regarding options will be followed.

(c) *Certification by County Committee.* Before a loan is approved, the County Committee will make the necessary certifications on Form FHA 440–2, "County Committee Certification." Before executing Form FHA 440–2, the County Committee will consider basic documents such as Form FHA 410–1, Form FHA 431–3, "Family Budget," or Form FHA 431–2, and, if applicable, Form FHA 431–1, "Long-Time Farm and Home Plan"; Form FHA 424–1 together with the plans and cost estimates for the proposed improvements; and Form FHA 422–1, "Appraisal Report," or when applicable, an estimate of the value of other property to be given as security. If the applicant is a senior citizen and the note is to be cosigned, information required from the cosigner and a statement by the County Supervisor regarding the cosigner also will be considered by the County Committee in making its certification. In order for the Committee to make its certification, members of the Committee may want to interview the applicant and want to see the farm or nonfarm tract on which the loan is to be made.

(1) If the Committee determines that it can make the necessary certification on Form FHA 440–2, the amount of the loan to be shown in the form is that for which the docket has been developed or a lesser amount if the Committee determines that the applicant cannot reasonably be expected to succeed with the loan as proposed.

(2) Ordinarily, the amount of the loan plus any other debts against the security will not be in excess of the recommended normal value of the security as shown on the appraisal report. In no event will a loan docket be developed when a loan plus any other debts against the security would be significantly in excess of the recommended normal value of the security. In an unusual case when the amount of a loan needed for success plus any other debts that will be against the security is slightly above the recommended normal value of the security and the County Committee and the County Supervisor believe that the loan should be made, Form FHA 440–2 may be completed. In such a case, the completed loan docket will be submitted to the State Office for a determination as to whether it is feasible to establish the normal value of the security above the appraiser's recommended normal value. If the loan approval official determines that the normal value is in excess of the appraiser's recommended normal value, he will record his determination of the normal value of the security on Form FHA 440–3.

§ 322.12 Preparation of loan docket.

(a) *Farm and Home Plans or Family Budget Form.* Form FHA 431–2 will be developed for all section 502 loans made on farms. Form FHA 431–1 also will be prepared whenever the applicant will receive intensive supervision. If an application is being considered early in the crop year for a borrower who has a current Form FHA 431–2, such form will be revised to show changes in the financial statement and significant changes in the planned operations; however, if the crop year is well advanced or completed, a farm and home plan will be developed for the ensuing year. If the applicant is or will be the owner of a nonfarm tract and he does not depend on farm income for a livelihood, Form FHA 431–3 will be used.

(b) *Agreements with prior lienholders.* When the loan is secured by a junior real estate mortgage, agreements with prior lienholders regarding enforcement of objectionable provisions of their liens or giving notice of foreclosure or assignment of their liens, or both, will be obtained when required by § 322.10(b).

(1) *Notice of foreclosure or assignment.* Such notice agreements will be obtained in States in which they are required.

(c) *Information concerning prior mortgage.* The applicant for a loan to be secured by a junior real estate or chattel mortgage will be required to furnish the County Supervisor, before the docket is assembled, a copy of each mortgage held by a prior lienholder and, if available, a copy of each secured note or other obligation. In addition, the County Supervisor will be furnished a current statement from the mortgagee showing the amount of unpaid principal secured by the mortgage, the amount of any accrued interest, whether the account is current or the amount of any delinquency, with interest and principal shown separately, and if a copy of the note is not furnished, its maturity date, payment schedule, interest rate, and a summary of any other provisions of the note. All these documents will be included in the docket for the information of the loan approval official. Any cost incident to obtaining them will be paid by the applicant.

(d) *Information about cosigner for a Senior Citizen loan.* When the note of a senior citizen borrower will be cosigned, information obtained from the cosigner will include a current financial statement, a statement of income and expenses, the nature of his employment, and a brief statement as to his employment history. The information required from the cosigner will be supplemented by a statement by the County Supervisor as to the cosigner's financial condition and reputation for paying his debts and any other information that would be of assistance to the loan approval official in determining the soundness of the loan. This information will be included in the docket.

(Sec. 502, 63 Stat. 433, as amended; 42 U.S.C. 1472)

§ 322.13 Loan approval.

(a) *Authority.* The State Director is authorized to approve or disapprove loans in accordance with this Subpart A. However, no initial or subsequent Section 502 loan may be approved by the State Director without the consent of the National Office if the amount of the loan plus the unpaid principal balance and any past-due interest on debts against the security for the loan and against any other real property of

the applicant would exceed $50,000, or the proposed loan, together with the principal balance owed on other Farmers Home Administration loans, would cause the total indebtedness to Farmers Home Administration to exceed $50,000. The State Director may redelegate, restrict, or revoke loan approval authority to: State Office employees other than Area Supervisors and to County Supervisors and GS–7 Assistant County Supervisors, in accordance with § 321.19 of this chapter, except that a senior citizen loan involving the purchase of real estate or a cosigner of the applicant's note may not be approved by the County Supervisor or an Assistant County Supervisor.

(b) *Loan approval action*—(1) *Approval or disapproval of a loan.* When a loan is approved, the loan approval official will:

(i) Indicate on all copies of Form FHA 440–3 any condition that must be met before the loan is closed and specify the security requirement that the applicant will need to meet, such as a first real estate lien, or a junior lien subject to certain prior liens, and so forth. If title evidence is required in accordance with Part 307 of this chapter or in accordance with any special requirements for the loan but is not included in the docket, the loan may be approved subject to the applicant's furnishing the required title evidence. When the applicant furnishes satisfactory title evidence, the County Supervisor will proceed with processing the loan, except that in those cases in which the title evidence does not comply with the conditions specified by the approval official, the docket will be reconsidered by the loan approval official.

(ii) Sign the approval certification on the original and two copies of Form FHA 440–3 and insert his title in the space below.

(iii) Sign Form FHA 440–1 and insert his title in the space provided.

(Sec. 502, 63 Stat. 433, as amended; 42 U.S.C. 1472)

(iv) When a loan is disapproved, the County Supervisor will notify the applicant of the disapproval of the loan and the reasons therefor.

§ 322.14 Actions subsequent to loan approval.

(a) *Increase or decrease in the amount of the loan.* If it becomes necessary that the amount of the loan be increased or decreased prior to loan closing, the County Supervisor will request that all distributed docket forms be returned to the County Office. The loan docket will be revised accordingly and reprocessed, except that, if the amount of the loan is decreased and there is no substantial change in the planned improvements, a new County Committee certification need not be obtained.

(b) *Cancellation of loan.* Loans may be canceled before loan closing as follows:

(1) The County Supervisor will prepare Forms FHA–903 or FHA 440–10, "Request for Cancellation of Loan." If the County Supervisor approved the loan, he will sign the request as approval official. If the County Supervisor did not approve the loan, he will send all copies of Forms FHA–903 or FHA 440–10 to the State Director.

(2) Interested parties will be notified of the cancellation as provided in Part 307 of this chapter.

(ii) Sign the approval certification on the original and two copies of Form FHA 440–3 and insert his title in the space below.

(iii) Sign Form FHA 440–1 and insert his title in the space provided.

(iv) When a loan is disapproved, the County Supervisor will notify the applicant of the disapproval of the loan and the reasons therefor.

(Sec. 502, 63 Stat. 433, as amended; 42 U.S.C. 1472)

§ 322.14 Actions subsequent to loan approval.

(a) *Increase or decrease in the amount of the loan.* If it becomes necessary that the amount of the loan be increased or decreased prior to loan closing, the County Supervisor will request that all distributed docket forms be returned to the County Office. The loan docket will be revised accordingly and reprocessed, except that, if the amount of the loan is decreased and there is no substantial change in the planned improvements, a new County Committee certification need not be obtained.

(b) *Cancellation of loan.* Loans may be canceled before loan closing as follows:

(1) The County Supervisor will prepare Forms FHA–903 or FHA 440–10, "Request for Cancellation of Loan." If the County Supervisor approved the loan, he will sign the request as approval official. If the County Supervisor did not approve the loan, he will send all copies of Forms FHA–903 or FHA 440–10 to the State Director.

(2) Interested parties will be notified of the cancellation as provided in Part 307 of this chapter.

(c) *Handling loan checks.* (1) The loan check will be handled in accordance with Part 303 of this chapter.

(d) *Property insurance.* (1) Buildings on the property which is to be taken as security for the loan will be insured in accordance with Part 306 of this chapter.

(2) When a loan is secured by a mortgage on chattels, and the loss of such chattels would jeopardize the interests of the Government, the County Supervisor may require the borrower to insure the chattels against hazards customarily covered by insurance in the area.

(e) *Loan closing actions.* The County Supervisor will review with the applicant the financial statement which was prepared at the time the docket was developed. If there have been significant changes in his financial conditions, the financial statement will be revised and initialed by the borrower and the County Supervisor. When an applicant's financial condition has changed to the extent that it appears that the loan would be unsound or improper the loan will not be closed. If a revised loan docket can be developed and if the County Supervisor is not authorized to approve the loan, it will be submitted to the loan approval official for reconsideration.

(1) A loan secured by a real estate mortgage (including a chattel mortgage on a leasehold) will be closed in accordance with Part 307 of this chapter.

(i) For a senior citizen loan on a farm or to purchase a dwelling not to be improved with loan funds, an additional covenant will be inserted in the mortgage as follows:

Borrower will personally occupy and use as his residence any dwelling on said property, constructed, improved, or purchased with the loan secured hereby and not rent or lease said dwelling unless the Government consents in writing to other occupancy or use or to a rental or lease.

(ii) Any special forms required in connection with a loan on a leasehold will be prepared or approved by the Office of the General Counsel or the State Director.

(iii) For a loan secured by a mortgage upon a leasehold the following language, or similar language which in the opinion of the Office of the General Counsel is legally adequate, will be inserted just before the legal description of the real estate:

All Borrower's right, title, and interest in and to the leasehold estate for a term of __ years beginning on _____, 19__, created and established by a certain Lease dated _____, 19__, executed by _____ as lessor(s), recorded on _____, 19__, in Book _____, page _____ of the _____ Records of said County and State, and any renewals and extensions thereof, and all Borrower's right, title, and interest in and to said Lease, covering the following real estate:

(iv) For a loan secured by a mortgage upon a leasehold an additional covenant will be inserted in the mortgage to read as follows:

Borrower will pay when due all rents and any and all other charges required by said Lease, will comply with all other requirements of said Lease, and will not surrender or relinquish, without the Government's written consent, any of Borrower's right, title, or interest in or to said leasehold estate or under said Lease while this instrument remains in effect.

(2) A loan on security other than real estate (except a chattel mortgage on a leasehold) will be closed in accordance with § 331.34 (b), (c), (d), and (f) of this chapter, and except that:

(i) Form FHA 440–17, "Promissory Note (Direct Loan)," will be used. The amount of the first installment will be determined by the County Supervisor after considering the immediate debt-paying ability of the borrower. The amount of the first installment may be less, but not more, than a regular annual installment. The note will be signed in accordance with Part 307 of this chapter. When a senior citizen note is being cosigned, the following sentence will be inserted in the space above the signatures: "The provisions of this note that the undersigned (a) personally occupy and use the dwelling and (b) refinance from other credit sources shall not apply to _____." The name of the cosigner will be written in the blank space and the inserted sentence will be initialed in

the margin by all persons signing the note.

(ii) Form FHA 30.____ (440–4) (State), "Crop and Chattel Mortgage for _____," will be adapted by deleting "Crop and" from the title, deleting "but not exceeding the rate of five percentum per annum" from the refinancing clause, and deleting any provisions for creating a crop lien. If the Uniform Commercial Code is in effect in the State, forms of financing statement and security agreement (Form FHA 440–4 (State)) or combined financing statement and security agreement (Form FHA 440–4 (State)) will be used instead of a chattel mortgage, after deleting any provisions that may encumber crops, and any reference to the Consolidated Farmers Home Administration Act of 1961. All deletions will be initialed by the borrower and the County Supervisor, Assistant County Supervisor, or Clerk before the instrument is executed. If an adapted form of chattel mortgage, financing statement, or security agreement is not adequate under State law, a special form approved by the Farmers Home Administration may be used. If any special assignment or pledge forms are needed in special cases, the Office of the General Counsel will prepare or approve the forms and issue any necessary closing instructions.

(3) When a loan is closed during December, the first installment will be collected at the time of loan closing.

(4) When the real estate mortgage is returned by the filing officials, the County Supervisor will conform the copy with the original showing the recording data including the date and place of recording and the book and page number, and deliver the conformed copy to the borrower. The original will be retained by the Farmers Home Administration unless it is retained by the filing official for the county records.

(f) *Assignment of income from real estate to be mortgaged.* Unless otherwise authorized by the National Office, income to be received by the borrower from royalties, leases, or other existing agreements under which the value of the real estate security will be depreciated will be assigned and disposed of in accordance with Subpart A of Part 372 of this chapter, including provisions for written consent of any prior lienholder. Also, when the County Supervisor deems it advisable, all or part of the income derived from nondepleting items such as bonus payments or annual delay rentals will be assigned and disposed of in the same manner, unless otherwise authorized by the National Office.

(1) For assignment of income, Form FHA 443–16, "Assignment of Income from Real Estate Security," will be used. If the form is legally inadequate it may be adapted with the approval of the Farmers Home Administration.

(2) The County Supervisor, upon the advice of the designated attorney, title insurance company, or Office of the General Counsel, as appropriate, may require the acknowledgment and recordation of the assignment. Any cost incident thereto will be borne by the borrower.

(g) *Owner's policy of title insurance.* If an owner's policy of title insurance is obtained, it will be delivered to the borrower as soon as it is received from the title insurance company.

(h) *Effective date of loan closing.* A loan secured by a real estate or chattel mortgage is closed when the mortgage is filed for record. In other cases a loan is closed when the loan funds are deposited in the supervised bank account or otherwise made available to the borrower after he executes and delivers the note and any other required instruments.

(i) *Water stock certificate or other such collateral.* When water stock certificates or other such collateral is a part of the security, it will be sent to the State Office for safekeeping.

§ 322.15 Subsequent section 502 loans.

A subsequent section 502 loan is a section 502 loan made to a borrower who has an existing Farm Housing or Rural Housing loan. Subsequent loans may be made for the same purposes and under the same conditions and limitations as initial loans.

(a) The subsequent loan will be processed in the same manner as initial loans, except that a new appraisal report will be required only when real estate will be taken as security and at least one of the following exists:

(1) The property was not appraised in connection with the initial loan.

(2) The latest appraisal report of the real estate is over two years old.

(3) The latest appraisal report is less than two years old but the appraiser recommended the normal market value rather than normal value.

(4) The physical characteristics of the property have changed significantly.

(5) The County Supervisor or loan approval official requests a new appraisal report.

(b) A subsequent Rural Housing loan may be secured wholly or partially by nonreal estate, provided that the amount of the nonreal estate portion of the subsequent loan plus the nonreal estate portion of the unpaid principal of the initial loan does not exceed $2,500, of which not more than $1,500 may be on a note-only basis.

Dated: June 15, 1964.

HOWARD BERTSCH,
Administrator,
Farmers Home Administration.

[F.R. Doc. 64–6095; Filed, June 18, 1964; 8:49 a.m.]

Title 5—ADMINISTRATIVE PERSONNEL

Chapter I—Civil Service Commission

PART 511—POSITION CLASSIFICATION UNDER THE CLASSIFICATION ACT SYSTEM

PART 534—PAY UNDER OTHER SYSTEMS

Miscellaneous Amendments

Section 511.201(b) is amended to show the exclusion from Part 511 and the Classification Act of 1949, as amended, of certain student laboratory assistants in the Department of Health, Education, and Welfare. Section 534.202(b) is amended to show the exclusion from the Federal Employees Pay Act and the Classification Act, and the maximum stipend prescribed for, certain student laboratory assistants in the Department of Health, Education, and Welfare. Effective on June 21, 1964, §§ 511.201(b) and 534.202(b) are amended as set out below.

1. The following item is added to paragraph (b) of § 511.201 as set out below:

§ 511.201 Coverage of and exclusions from the Classification Act.

* * * * *

(b) *Exclusions.* * * *

Student laboratory assistants, Department of Health, Education, and Welfare, approved training after a minimum of two years high school level training.

(Sec. 2, 61 Stat. 727 and sec. 1101, 63 Stat. 971; 5 U.S.C. 1052, 1072)

2. The following item is added to paragraph (b) of § 534.202 as set out below.

§ 534.202 Maximum stipends.

* * * * *

(b) * * *

Student laboratory assistants, Department of Health, Education, and Welfare: Approved training after a minimum of two years high school level training	L–A

(Secs. 1, 2, 3, 61 Stat. 727; 5 U.S.C. 902, 1051, 1052)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] MARY V. WENZEL,
Executive Assistant to the Commissioners.

[F.R. Doc. 64–6092; Filed, June 18, 1964; 8:49 a.m.]

Title 7—AGRICULTURE

Chapter VII—Agricultural Stabilization and Conservation Service (Agricultural Adjustment), Department of Agriculture

SUBCHAPTER B—FARM MARKETING QUOTAS AND ACREAGE ALLOTMENTS

[Amend. 2]

PART 729—PEANUTS

Subpart—Allotment and Marketing Quota Regulations for Peanuts of the 1963 and Subsequent Crops

1. *Basis and purpose.* a. The amendment contained herein is issued pursuant to the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1281 et seq.), to revise the Allotment and Marketing Quota Regulations for Peanuts of the 1963 and Subsequent Crops (27 F.R. 11920, 28 F.R. 11811).

The amendment (1) permits an adjustment in the final acreage of peanuts on a farm in cases where, because of abnormal conditions affecting acreage, the acreage planted is less than 75% of the farm allotment, provided the farm operator files a request for such an ad-

justment prior to November 1 of the current year, (2) provides that an allotment shall not be established for a new farm from acreage made available from the new farm reserve unless the farm is operated by the owner thereof who must have had experience in producing, harvesting and marketing peanuts, either as a sharecropper, tenant or farm operator during at least two of the five years immediately preceding the year for which the new farm allotment is requested, (3) provides that land acquired by an agency having the right of eminent domain for which the entire peanut allotment was pooled, which is subsequently returned to agricultural production, shall not be eligible for a new farm allotment for a period of three years from the date the former owner was displaced, (4) provides that a written request must be filed in all States by the farm owner or operator to obtain reapportionment of released peanut acreage, and (5) changes for all counties in California, the closing date for voluntarily releasing peanut acreage which will not be used on the farm to which allotted and the date by which a written request must be filed for reapportionment of released acreage.

b. Public notices of intention to issue this amendment were given (29 F.R. 3439, 5513) in accordance with the provisions of the Administrative Procedure Act (5 U.S.C. 1001–1011) and due consideration has been given to recommendations received in response to such notices.

c. The amendment to § 729.1424(c) contained herein shall be applicable to the 1964 and subsequent crops and the other amendments contained herein shall be applicable to the 1965 and subsequent crops.

2. The Allotment and Marketing Quota Regulations for Peanuts of the 1963 and Subsequent Crops (27 F.R. 11920, 28 F.R. 11811) are hereby amended as follows:

a. The first two sentences of paragraph (c) of § 729.1424 are amended to read as follows:

§ 729.1424 Determination of farm peanut history acreage.

* * * * *

(c) *Computation of history acreage.* If, for any year, the full allotment is not preserved as peanut history acreage under paragraph (b) of this section, the farm peanut history acreage for such year shall be the sum of the following acreages, but not in excess of the farm allotment for such year:

(1) The final acreage, adjusted to compensate for abnormal conditions affecting acreage, if the county committee determines that such action is necessary to maintain equitable allotments: *Provided,* That, the farm operator files a written request for such an adjustment at the office of the county committee prior to November 1 of the current year.

b. Section 729.1432 is amended to read as follows:

§ 729.1432 Conditions of eligibility for new farm allotment.

(a) A farm which includes land acquired by an agency having the right of eminent domain for which the entire peanut allotment was pooled pursuant to Part 719 of this chapter, which is subsequently returned to agricultural production, shall not be eligible for a new farm peanut allotment for a period of three years from the date the former owner was displaced from the acquired farm.

(b) An allotment shall not be established for a new farm from acreage made available from the new farm national reserve unless each of the following conditions is met;

(1) A written application for a new farm allotment is filed by the farm operator at the office of the county committee on or before February 15 of the year for which application for an allotment is being filed.

(2) The farm shall be operated by the owner thereof. A person who owns only part of a farm cannot be considered the owner of the farm except that both husband and wife shall be considered the owner of the farm if the farm is jointly owned by such husband and wife;

(3) The farm is the only farm in the United States, owned or operated by the farm operator for which a farm peanut allotment is established for the current year;

(4) The type of soil and topography of the available land on the farm for which the allotment is requested is suitable for the production of peanuts, and the continuous production of peanuts on the farm will not result in an undue erosion hazard;

(5) The farm operator shall own, or otherwise have readily available, adequate equipment and any other facilities of production (including irrigation water) necessary to the successful production of peanuts on the farm;

(6) The operator expects to obtain, during the current year, more than 50 percent of his income from the production of agricultural commodities or products from the farm for which the new farm allotment application is filed. In making this computation of income from the farm, no value will be allowed for the estimated return from the production of the requested allotment. However, in addition to the value of agricultural products sold from the farm, credit will be allowed for the estimated value of home gardens, livestock and livestock products, poultry, or other agricultural products produced for home consumption or other use on the farm. Where the farm operator is a partnership, each partner must expect to obtain, during the current year, more than 50 percent of his income from agricultural commodities or products from the farm; where the farm operator is a corporation, such corporation must have no major corporate purpose other than operation and ownership of such farm, and the officers and general manager of the corporation must expect to obtain more than 50 percent of their income, including dividends and salary, from the corporation;

(7) The farm operator shall have had experience in producing, harvesting and marketing peanuts either as a sharecropper, tenant, or farm operator during at least two of the five years immediately preceding the year for which the new farm allotment is requested. In making a determination of any person's experience in growing peanuts, no credit shall be given for the person's interest in peanuts grown on a farm for which no farm peanut allotment was established for such year.

c. Paragraph (a) and paragraph (b), as amended, of § 729.1433 are amended to read as follows:

§ 729.1433 Additional acreage for new farms.

* * * * *

(a) A written application for an allotment is filed by the farm operator at the office of the county committee on or before March 1 of the year for which an allotment is being requested; and,

(b) The conditions prescribed in paragraphs (a) and (b)(2) through (6) of § 729.1432 are met.

d. Paragraph (a) of § 729.1435, as amended, is amended to establish April 1 as the closing date for all counties in California for voluntarily surrendering in writing to the county committee peanut acreage which will not be used on the farm to which allotted.

e. Paragraph (b), as amended, of § 729.1435 is amended to read as follows:

§ 729.1435 Release and reapportionment.

* * * * *

(b) *Reapportionment of released acreage allotment.* The acreage released under paragraph (a) of this section may be reapportioned by the county committee to other farms in the same county receiving allotments in amounts determined by the county committee to be fair and reasonable on the basis of tillable acreage available; labor and equipment available for the production of peanuts; crop rotation practices; and soil and other physical factors affecting the production of peanuts; except that any acreage allotment released from a farm which is covered in whole or in part by a Conservation Reserve Contract or for which a Cropland Conversion Program Agreement is in effect or has been applied for, shall not be reapportioned to any other farm. Notwithstanding any other provision of this paragraph, a farm shall be eligible to receive a reapportionment of released acreage only if a written request is filed by the farm owner or operator at the office of the county committee not later than the applicable of the dates specified below.

State and Closing Date
Alabama, March 15.
Arkansas, May 15.
Arizona, March 15.
California, April 1.
Florida, March 15.
Georgia, April 1.
Louisiana, July 1.
Mississippi, May 15.
Missouri, May 25.
New Mexico, May 10.
North Carolina, April 15.
Oklahoma, June 7.
South Carolina, May 10.
Tennessee, April 1.
Virginia, April 15.
Texas (see following list).

Texas

In this State the same closing dates are applicable for purposes of both paragraphs

(a) and (b) of this section. These closing dates, by zones within the State, are as listed below.

March 1 for Zone 1, comprised of the counties of:

Aransas.	Karnes.
Atascosa.	Kendall.
Austin.	Kenedy.
Bandera.	Kerr.
Bee.	Kinney.
Bexar.	Kleberg.
Brazoria.	La Salle.
Brooks.	Lavaca.
Calhoun.	Liberty.
Cameron.	Live Oak.
Chambers.	McMullen.
Colorado.	Matagorda.
Comal.	Maverick.
De Witt.	Medina.
Dimmit.	Nueces.
Duval.	Orange.
Edwards.	Real.
Fort Bend.	Refugio.
Frio.	San Patricio.
Galveston.	Starr.
Goliad.	Uvalde.
Gonzales.	Val Verde.
Guadalupe.	Victoria.
Hardin.	Waller.
Harris.	Webb.
Hidalgo.	Wharton.
Jackson.	Willacy.
Jefferson.	Wilson.
Jim Hogg.	Zapata.
Jim Wells.	Zavala.

April 4 for Zone 2, comprised of the counties of:

Anderson.	Harrison.
Andrews.	Hays.
Angelina.	Henderson.
Archer.	Hill.
Bastrop.	Hood.
Bell.	Hopkins.
Blanco.	Houston.
Borden.	Howard.
Bosque.	Hudspeth.
Bowie.	Hunt.
Brazos.	Irion.
Brewster.	Jack.
Brown.	Jasper.
Burleson.	Jeff Davis.
Burnet.	Johnson.
Caldwell.	Jones.
Callahan.	Kaufman.
Camp.	Kimble.
Cass.	Lamar.
Cherokee.	Lampasas.
Clay.	Lee.
Coke.	Leon.
Coleman.	Limestone.
Collin.	Llano.
Comanche.	Loving.
Concho.	McCulloch.
Cooke.	McLennan.
Coryell.	Madison.
Crane.	Marion.
Crockett.	Martin.
Culberson.	Mason.
Dallas.	Menard.
Dawson.	Midland.
Delta.	Milam.
Denton.	Mills.
Eastland.	Mitchell.
Ector.	Montague.
Ellis.	Montgomery.
El Paso.	Morris.
Erath.	Nacogdoches.
Falls.	Navarro.
Fannin.	Newton.
Fayette.	Nolan.
Fisher.	Palo Pinto.
Franklin.	Panola.
Freestone.	Parker.
Gaines.	Pecos.
Gillespie.	Polk.
Glasscock.	Presidio.
Grayson.	Rains.
Gregg.	Reagan.
Grimes.	Red River.
Hamilton.	Reeves.
Robertson.	Terrell.
Rockwall.	Titus.
Runnels.	Tom Green.
Rusk.	Travis.
Sabine.	Trinity.
San Augustine.	Tyler.
San Jacinto.	Upshur.
San Saba.	Upton.
Schleicher.	Van Zandt.
Scurry.	Walker.
Shackelford.	Ward.
Shelby.	Washington.
Smith.	Wichita.
Somervell.	Williamson.
Stephens.	Winkler.
Sterling.	Wise.
Sutton.	Wood.
Tarrant.	Young.
Taylor.	

April 18 for Zone 3, comprised for the counties of:

Armstrong.	Hockley.
Bailey.	Hutchinson.
Baylor.	Kent.
Briscoe.	King.
Carson.	Knox.
Castro.	Lamb.
Childress.	Lipscomb.
Cochran.	Lubbock.
Collingsworth.	Lynn.
Cottle.	Moore.
Crosby.	Motley.
Dallam.	Ochiltree.
Deaf Smith.	Oldham.
Dickens.	Parmer.
Donley.	Potter.
Floyd.	Randall.
Foard.	Roberts.
Garya.	Sherman.
Gray.	Stonewall.
Hale.	Swisher.
Hall.	Terry.
Hansford.	Throckmorton.
Hardeman.	Wheeler.
Hartley.	Wilbarger.
Haskell.	Yoakum.
Hemphill.	

(Secs. 358, 375, 55 Stat. 88, as amended, 52 Stat. 66, as amended; 7 U.S.C. 1358, 1375)

Effective date. 30 days from the date of publication in the FEDERAL REGISTER.

Signed at Washington, D.C., on June 16, 1964.

H. D. GODFREY,
Administrator, Agricultural Stabilization and Conservation Service.

[F.R. Doc. 64-6097; Filed, June 18, 1964; 8:49 a.m.]

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Tree Nuts), Department of Agriculture

[Apricot Reg. 3]

PART 922—APRICOTS GROWN IN DESIGNATED COUNTIES IN WASHINGTON

Limitation of Shipments

§ 922.303 Apricot Regulation 3.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 922, as amended (7 CFR Part 922), regulating the handling of apricots grown in designated counties in Washington, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations of the Washington Apricot Marketing Committee, established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of apricots, in the manner herein provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001-1011) in that, as hereinafter set forth, the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient; a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective not later than June 22, 1964. A reasonable determination as to the supply of, and the demand for, such apricots must await the development of the crop and adequate information thereon was not available to the Washington Apricot Marketing Committee until May 26, 1964; recommendation as to the need for, and the extent of, regulation of shipments of such apricots was made at the meeting of said committee on May 26, 1964, after consideration of all available information relative to the supply and demand conditions for such apricots, at which time the recommendation and supporting information were submitted to the Department; necessary supplemental data for consideration in connection with the specifications of the provisions were not available until June 8, 1964; shipments of the current crop of such apricots will begin on or about June 22, 1964, and this section should be applicable, insofar as practicable, to all shipments of such apricots in order to effectuate the declared policy of the act; and compliance with the provisions of this section will not require of handlers any preparation therefor which cannot be completed by the effective time hereof.

(b) *Order.* (1) During the period beginning at 12:01 a.m., P.s.t., June 22, 1964, and ending at 12:01 a.m., P.s.t., October 1, 1964, no handler shall handle any container of apricots unless:

(i) Such apricots grade not less than Washington No. 1: *Provided,* That such apricots are at least reasonably uniform in color;

(ii) Such apricots measure not less than 1⅝ inches in diameter: *Provided,* That apricots of the Blenheim, Blenril, and Tilton varieties when packed in unlidded wooden boxes may measure not less than 1¼ inches; and: *Provided, further,* That not more than 10 percent, by count, of such apricots may fail to meet the applicable minimum diameter requirement; and

(iii) Such apricots when packed in lidded containers are row-faced: *Provided,* That this requirement shall not

apply to apricots in experimental containers approved pursuant to § 922.110.

(2) All apricots handled during the period specified in this regulation are subject also to all applicable container restrictions which are in effect pursuant to this part during such period.

(3) Notwithstanding any other provision of this section, any individual shipment of apricots which (i) does not, in the aggregate, exceed 150 pounds may be handled without regard to the restrictions specified in this paragraph (grade, size, pack, and container) or in §§ 922.41 (Assessments) or 922.55 (Certification); (ii) is sold at the orchard, is in excess of 150 pounds but not in excess of 500 pounds, and is for home use only and not for resale in commercial channels may be handled without regard to the restrictions in § 922.55 (Certification) or the pack and container requirements of this paragraph: *Provided*, That the fruit so shipped meets the grade and size requirements of this paragraph and is subject to § 922.41 (Assessments) and is reported to the committee on forms furnished by the committee in the manner specified therein.

(4) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said amended marketing agreement and order; "diameter" and "Washington No. 1" shall have the same meaning as when used in the Washington State Department of Agriculture Official Standards for Apricots (1958); and "reasonably uniform in color" means that the apricots in the individual container do not show sufficient variation in color to materially affect the general appearance of the apricots.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: June 15, 1964.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64-6060; Filed, June 18, 1964; 8:45 a.m.]

Chapter XIV—Commodity Credit Corporation, Department of Agriculture

SUBCHAPTER B—LOANS, PURCHASES, AND OTHER OPERATIONS

[C.C.C. Grain Price Support Reseal Loan Regulations, Extensions 1 and 2]

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

Subpart—1961-Crop Reseal Loan Programs for Corn and Wheat, Extension 1 and 1961-Crop Grain Sorghum, Extension 2

Reseal loan programs have been announced for the 1961 crops of corn, wheat and grain sorghum for the 1964–65 storage period. These programs provide under certain conditions for the extension of 1961-crop farm-storage loans. The 1961 C.C.C. Grain Price Support Bulletin 1 (26 F.R. 2106) containing the general requirements with respect to price support operations for grains and related commodities produced in 1961, as supplemented for corn, wheat and grain sorghum by bulletins containing the specific requirements for the 1961-crop price support program for these commodities is hereby further supplemented as follows:

Sec.
1421.3431 Applicable sections of 1961 C.C.C. Grain Price Support Bulletin 1 and Commodity Supplements.
1421.3432 Availability.
1421.3433 Eligible commodity.
1421.3434 Commingling.
1421.3435 Approved forms.
1421.3436 Quantity eligible for resealing.
1421.3437 Storage payments.
1421.3438 Maturity.
1421.3439 Delegation of authority.

AUTHORITY: The provisions of this subpart issued under sec. 4, 62 Stat. 1070, as amended; 15 U.S.C. 714b. Interpret or apply sec. 5, 62 Stat. 1072, secs. 101, 105, 301, 401, 63 Stat. 1051, 1054, 15 U.S.C. 714c; 7 U.S.C. 1421, 1441, 1447.

§ 1421.3431 Applicable sections of 1961 C.C.C. Grain Price Support Bulletin 1 and Commodity Supplements.

The following sections of the 1961 C.C.C. Grain Price Support Bulletin 1, as amended, published in 26 F.R. 2106 shall be applicable to the reseal loan programs for the 1961 crops of corn, grain sorghum and wheat: §§ 1421.101, 1421.104, 1421.107(a), 1421.109, 1421.111 through 1421.118, 1421.119 except (b) and (c) and 1421.120 through 1421.122. Applicable sections of the individual commodity supplements are as follows: For corn, §§ 1421.239, 1421.240, 1421.241, 1421.243, 1421.246 (except (b), (c) and (g)) and 1421.247 (26 F.R. 7248, 10031). For grain sorghum, §§ 1421.329, 1421.330, 1421.331, 1421.333, 1421.336 (except (c), (d) and (h)) and 1421.337 (26 F.R. 5107, 5569). For wheat, §§ 1421.139, 1421.140, 1421.141, 1421.143, 1421.146 (except (c), (d) and (h)) and 1421.147 (26 F.R. 3873, 6697). Other sections of the 1961 C.C.C. Grain Price Support Bulletin 1 and supplements thereto for corn, grain sorghum and wheat shall be applicable to the extent indicated in this subpart. Any reference in this subpart to a section of another bulletin shall be deemed to refer to the section and any amendments thereto.

§ 1421.3432 Availability.

(a) *Area and scope.* The extended reseal loan programs will be available in those States where the applicable 1961 crop commodity is under reseal loan, and the ASC State committee determines that the commodity can be safely stored on the farm for the period of the extended reseal loan and that it will be advantageous to producers and CCC to permit producer to extend reseal loans.

(b) *When to apply.* The producer must make application on or before June 30, 1964 for grain sorghum and wheat and on or before October 31, 1964 for corn.

§ 1421.3433 Eligible commodity.

To be eligible for an extended reseal loan the commodity must be in farm storage presently under reseal loan and must meet the applicable requirements listed below:

(a) Corn: The corn (1) must meet the requirements set forth in § 1421.238 (a), (b), (c), and (d); (2) must grade No. 3 or better or No. 4 on the factor of test weight only but otherwise No. 3 or better; (3) must contain not in excess of 16.0 percent moisture in the case of ear corn or in excess of 14.0 percent moisture in the case of shelled corn; and (4) must not grade Weevily.

(b) Grain sorghum: The grain sorghum (1) must meet the requirements set forth in § 1421.328 (a) and (b); (2) must be of any class grading No. 4 or better, or No. 4 Smutty or better; (3) must not grade Weevily or contain mercurial compounds or other substances poisonous to man or animals; and (4) must not be in excess of 13 percent moisture.

(c) Wheat: The wheat (1) must meet the eligibility requirements set forth in § 1421.138 (a), (b) and (d); (2) must grade No. 3 or better except that it may grade No. 5 or better on the factor of test weight and because of containing Duram and Red Duram (3) may be wheat of any class except Duram and if the wheat is of the class Mixed Wheat, it must consist of mixtures of grades of eligible wheat which are the natural products of the field; and (4) must not grade Tough, Weevily, Ergoty, or Treated.

(d) An inspection of the grain shall be made by a representative of the county committee prior to approval of the extension of the reseal loan.

(e) Consent for storage: The producer shall make appropriate arrangements so that the mortgaged commodity may remain in the structures in which it is stored until 60 days after the maturity date of the reseal loan, without any cost to CCC other than the storage payments provided in § 1421.3438.

§ 1421.3434 Commingling.

(a) *When authorized.* If authorized by the State committee, the county committee may permit a producer to commingle quantities of a commodity which are under more than one loan and which are deemed safe for commingling by the county committee, subject to the following conditions:

(1) Hard wheat which is subject to a sedimentation premium or discount shall not be commingled.

(2) A commodity of not more than three crop years may be commingled.

(3) The commodity to be commingled must be of the same class and meet the applicable eligibility requirements before commingling.

(4) Commodities owned by more than one producer may be commingled only if the original loan was made jointly to the same producers and the other requirements of this section are complied with.

(b) *Special conditions.* Notwithstanding any other provision of these regulations, the following provisions shall apply in the event quantities of a commodity covered by more than one loan are commingled:

(1) Partial deliveries of the commingled commodity shall not be permitted.

(2) If partial redemptions of the commingled commodity are made in accordance with other provisions of these regulations, the quantity redeemed shall be prorated to each loan on the basis of the ratio of the quantity on which the loan was made to the total quantity on which all the loans covering the commingled commodities were made. The dollar amount to be credited to each loan shall be based on the amount of the loan represented by the quantity determined to have been redeemed from the loan.

(3) Producers whose commodities are commingled shall be jointly and severally responsible for the amount of each loan represented by the commingled commodity.

(4) For settlement purposes, if a commodity of more than one crop year has been commingled the quantity delivered shall be prorated to each loan based on the ratio that the quantity on which the loan was made bears to the quantity covered by all the loans on the commingled commodity. If less than the total quantity covered by the loan is delivered, the quantity delivered shall be applied first to the loan having the commodity with the lowest basic support rate up to the total amount on which the loan was made, and the balance, if any, shall be applied to the other loans proceeding successively in the order of the loans having increasingly higher basic support rates.

(5) In the case of 1962 crop grain sorghum commingled with grain sorghum of other crop years, if any grain sorghum delivered to CCC grades No. 1, the quantity of No. 1 grade to be credited as a delivery under the 1962 crop loan shall be obtained by prorating each loan a portion of the quantity of No. 1 grade grain sorghum delivered the same manner as the total quantity of grain sorghum delivered was prorated pursuant to the preceding subparagraph of this section. In other cases where a commodity of different grades and qualities is delivered, the quantity of each grade and quality to be credited to each loan shall be as determined by the county office, provided that the total quantity credited to the loan shall equal the amount determined under the preceding subparagraph of this section.

§ 1421.3435 Approved forms.

(a) *Forms requirements.* The approved forms, which together with the provisions of this subpart govern the rights and responsibilities of the producer, shall consist of Producer's Note and Supplemental Loan Agreement secured by a Commodity Chattel Mortgage, and such other forms and documents as may be prescribed by CCC. Notes and chattel mortgages must have State documentary revenue stamps affixed thereto where required by law.

(b) *New forms.* If required by State law, or if quantities of a commodity under two or more loans are commingled under the provisions of § 1421.3434, a new Producer's Note and new Chattel Mortgage shall be completed when a farm-storage loan is extended. Where new forms are not completed, extension of farm-storage loans shall not affect the rights of CCC, including its right to accelerate the maturity date of the note, and the rights and responsibilities of the producer as set forth in this subpart and in the original approved forms completed by the producer.

§ 1421.3436 Quantity eligible for reseal ing.

(a) *Quantity under loan.* The quantity of the commodity under loan eligible for reseal shall be the quantity shown on the original note and chattel mortgage less (1) any quantity delivered not including the quantity represented by overdelivery for which overrun payment is made and (2) the quantity redeemed.

(b) *Limitation on corn and grain sorghum.* Notwithstanding the provisions of paragraph (a) of this section, in the case of corn and grain sorghum the total quantity on which price support shall be made available and on which a storage payment may be earned shall not exceed the maximum quantity as specified in § 1421.905 of 1961 C.C.C. Feed Grain Bulletin A (26 F.R. 6263).

§ 1421.3437 Storage payments.

(a) *Full storage payment for 1963–64 reseal period.* (1) A producer who extends his reseal loan for the 1964–65 period will at the time of such extension receive a payment for storage earned during the 1963–64 reseal period. This payment will be disbursed by the ASCS county office and will be 14 cents per bushel for corn and wheat and 24 cents per hundredweight for grain sorghum less any storage payment previously received by the producer from CCC for the 1963–64 reseal period.

(2) Upon delivery of the 1961-crop commodity the actual quantity of such commodity will be determined by weighing. The storage payment earned by the producer covering the 1962–63 and 1963–64 reseal periods will be recomputed on the basis of the actual quantity determined to have been covered by the extended reseal loan. Any amount due the producer for such storage on the quantity of the eligible commodity delivered in excess of the quantity stated in the extended loan documents will be credited to the producer's account in settlement of the loan. The amount of any over-payment which is determined to have been made to the producer shall be collected from the producer.

(3) No storage payment will be made for the 1963–64 reseal period (i) where the producer has made any false representations in the loan documents or in obtaining the loan, or in deliveries or settlement under the loan, (ii) where during the 1963-64 reseal period the commodity has been abandoned or the commodity was damaged or otherwise impaired due to negligence on the part of the producer, or (iii) where during or prior to the 1963-64 reseal period the commodity was converted by the producer or at any time subsequent thereto there was conversion of the commodity by the producer with intent to defraud CCC.

(b) *Full storage payments for the 1964–65 reseal period.* A storage payment of 14 cents per bushel for corn and wheat and 24 cents per hundredweight for grain sorghum will be made to the producer if he redeems the commodity from loan or delivers the commodity under loan on or after July 31, 1965 for corn and March 31, 1965 for grain sorghum and wheat. Such dates are referred to in this section as "The maturity date for full storage payments".

(c) *Prorated storage payment for the 1964–65 reseal period—(1) Early deliveries and CCC assumed losses.* (i) In the case of deliveries earlier than the maturity date for full storage payments, a storage payment will be computed beginning 60 days subsequent to the latest maturity date applicable to the loan prior to the extension and ending on the earlier of the date delivery is completed or the date specified for delivery by the county office. (ii) In the case of losses assumed by CCC the storage payment will be computed for the period beginning on the date as set forth in subdivision (i) and ending on the date the loss occurs. (iii) The daily rates for these computations should be $0.00046 per bushel for corn and wheat and $0.00079 per cwt. for grain sorghum, but shall not exceed in the aggregate the applicable amount as specified in paragraph (b) of this section.

(2) *Redemptions prior to maturity.* On redemptions prior to the maturity date for full storage payments, a storage payment will be made to the producer. Such storage payment will be determined according to the length of time the commodity was in store for the period beginning on the day following the latest maturity date applicable to the loan prior to the extension and ending on the date of repayment. The prorated payment will be computed at the daily rate of $0.00038 for corn and wheat and of $0.00066 per cwt. for grain sorghum but not to exceed the applicable amount specified in paragraph (b) of this section.

(d) *Quantity eligible.* Except in the case of partial loans, the quantity eligible for storage payment under paragraphs (a) and (b) of this section shall be (1) in the case of delivery to CCC, or losses assumed by CCC the entire quantity in the bin, (2) in the case of redemptions, the entire quantity in the bin but not to exceed the measured quantity adjusted for test weight. The quantity eligible for a storage payment in the case of partial loan shall not exceed the quantity under loan.

(e) *No storage payments.* Nothwithstanding the provisions of this section in no case will any storage payment be made for the 1964–65 reseal period (1) where the producer has made any false representation in the loan documents, in obtaining the loan, or in settlement of the loan; (2) where the commodity has been abandoned, (3) where there has been conversion on the part of the producer, or (4) where the commodity was damaged or otherwise impaired due to negligence on the part of the producer. If a producer receives payment of any amount to which he is not entitled, he shall refund such amount plus interest thereon promptly upon demand.

§ 1421.3439 Maturity.

Loans will mature on demand but not later than March 31, 1965, for grain sorghum and wheat and July 31, 1965 for corn.

§ 1421.3440 Delegation of authority.

No delegation herein to a State or county committee shall preclude the Executive Vice President, CCC, or his designee from determining any question arising under the program or from reversing or modifying any determination made by a State or county committee, or ASCS commodity office or the ASCS Data Processing Center.

Effective date. Upon publication in the FEDERAL REGISTER.

Signed at Washington, D.C., on June 15, 1964.

RAY FITZGERALD,
Acting Executive Vice President, Commodity Credit Corporation.

[F.R. Doc. 64-6062; Filed, June 18, 1964; 8:46 a.m.]

[1960 C.C.C. Grain Price Support Reseal Loan Regulations, Extension 2]

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

Subpart—1960-Crop Reseal Loan Programs for Corn and Wheat, Extension 2

Extended reseal loan programs have been announced for the 1960 crops of corn and wheat for the 1964–65 storage period. These programs provide under certain conditions, for the extension of 1960 farm-storage loans. The 1960 C.C.C. Grain Price Support Bulletin 1 (25 F.R. 2380) containing the general requirements with respect to price support operations for grains and similarly handled commodities produced in 1960, as supplemented for corn and wheat by regulations containing the specific requirements for the 1960-crop price support programs for these commodities are hereby further supplemented as follows:

Sec.
1421.3451 Applicable sections of 1960 C.C.C. Grain Price Support Bulletin 1 and commodity supplements.
1421.3452 Availability.
1421.3453 Eligible commodity.
1421.3454 Commingling.
1421.3455 Approved forms.
1421.3456 Quantity eligible for extended reseal loan.
1421.3457 Storage payments.
1421.3458 Maturity.
1421.3459 Death, incompetency, or disappearance.
1421.3460 Delegation of authority.
1421.3461 Fraud in settlement of loans.

AUTHORITY: The provisions of this subpart issued under sec. 4, 62 Stat. 1070, as amended; 15 U.S.C. 714b. Interpret or apply sec. 5, 62 Stat. 1072, secs. 101, 105, 301, 401, 63 Stat. 1051, 1054, sec. 308, 70 Stat. 206; 15 U.S.C. 714c; 7 U.S.C. 1421, 1441, 1442, 1447.

§ 1421.3451 Applicable sections of 1960 C.C.C. Grain Price Support Bulletin 1 and commodity supplements.

The following sections of the 1960 C.C.C. Grain Price Support Bulletin 1, as amended, published in (25 F.R. 2380) shall be applicable to the 1960 reseal loan programs for corn and wheat: §§ 1421.5001, 1421.5004, 1421.5007(a), 1421.5009, 1421.5011, 1421.5012, 1421.5013(b), 1421.5014, 1421.5015(a), 1421.5016(a), 1421.5017, 1421.5018, 1421.5019 (a), (b), (f), 1421.5020, and 1421.5021. Applicable sections of the individual commodity supplements are as follows: for corn §§ 1421.5139, 1421.5140, 1421.5141, 1421.5143, 1421.5146 (a)(1), (d), (e), and (f), and 1421.5147 (25 F.R. 5563, 10078); for wheat, §§ 1421.5039, 1421.5040, 1421.5041, 1421.5043, 1421.5046 (a)(1), (b) (2), (3), (4), and (5), (e), (f) and (g), and 1421.5047 (25 F.R. 3915, 7731). Other sections of the 1960 C.C.C. Grain Price Support Bulletin 1 and supplements thereto for corn and wheat shall be applicable to the extent indicated in this subpart. Any reference in this subpart to a section of another bulletin shall be deemed to refer to the section and any amendments thereto.

§ 1421.3452 Availability.

(a) *Area and scope.* The extended reseal loan program will be available in those States where 1960-crop corn and wheat is under reseal loan and where ASC State committees determine that the commodity can be safely stored on farms for the period of the reseal loan and that it will be advantageous to producers and CCC to permit producers to obtain reseal loans.

(b) *When to apply.* The producer must make application on or before October 31, 1964 for corn, and on or before June 30, 1964 for wheat.

§ 1421.3453 Eligible commodity.

(a) *Requirements of eligibility.* The commodity (1) must be in farm storage presently under reseal loan and (2) must meet the following eligibility requirements:

Corn: The corn (1) must meet the requirements set forth in § 1421.5138 (a), (b), (c), and (d); (2) must grade No. 3 or better or No. 4 on the factor of test weight only but otherwise No. 3 or better; (3) must contain not in excess of 16.0 percent moisture in the case of ear corn nor in excess of 14.0 moisture in the case of shelled corn; and (4) must not grade weevily.

Wheat: The wheat (1) must meet the requirements set forth in § 1421.5038 (a), (b), and (d); (2) must grade No. 3 or better except it may grade No. 5 or better on the factor of test weight and because of containing Durum and Red Durum; (3) may be wheat of any class except Durum and if the wheat is of the class Mixed Wheat it must consist of mixtures of grades of eligible wheat which are natural products of the field; and (4) must not grade Tough, Weevily, Ergoty, or Treated.

(b) *Inspection.* An inspection of the grain shall be made by a representative of the county committee prior to approval of the commodity for an extended reseal loan.

(c) *Consent for storage.* The producer shall make appropriate arrangements so that the mortgaged commodity may remain in the structures in which it is stored until 60 days after the maturity date of the reseal loan, without any costs to CCC other than the storage payments provided in § 1421.3457.

§ 1421.3454 Commingling.

(a) *When authorized.* If authorized by the State committee, the county committee may permit a producer to commingle a commodity which is under more than one loan and which is deemed safe for commingling by the county committee, subject to the following conditions: (1) Hard Wheat which is subject to a sedimentation premium or discount shall not be commingled (2) A commodity of not more than three crop years may be commingled (3) The commodity to be commingled must be of the same class and meet the applicable eligibility requirements before commingling (4) Commodities owned by more than one producer may be commingled only if the original loan was made jointly to the same producers and the other requirements of this section are complied with.

(b) *Special conditions.* Notwithstanding any other provision of these regulations, the following provisions shall apply if commodities covered by more than one loan are commingled: (1) Partial deliveries of the commingled commodities shall not be permitted (2) If partial redemptions are made in accordance with other provisions of these regulations, the quantity redeemed shall be prorated to each loan on the basis of the rate of the quantity on which the loan was made to the total quantity on which all the loans secured by the commingled commodities were made; and the dollar amount to be credited to each loan shall be based on the amount of the loan represented by the quantity determined to have been redeemed from the loan (3) Producers whose commodities are commingled shall be jointly and severally responsible for the amount of each loan secured by the commingled commodities (4) For settlement purposes, if a commodity of more than one crop year has been commingled, the quantity delivered shall be prorated to each loan based on the ratio that the quantity on which the loan was made bears to the quantity covered by all the loans on the commingled commodity; and if less than the total quantity covered by all such loans is delivered, the quantity delivered shall be applied first to the loan having the commodity with the lowest basic support rate up to the total amount on which the loan was made, and the balance, if any, shall be applied to the other loans proceeding successively in order of the loans having increasingly higher basic support rates (5) In cases where a commodity of different grades and qualities is delivered, the quantity of each grade and quality to be credited to each loan shall be determined by the county office, provided that the total quantity credited to the loan shall equal the amount determined under subparagraph (4) of this paragraph.

§ 1421.3455 Approved forms.

(a) *Forms required.* The approved forms, which together with the provisions of this subpart govern the rights and responsibilities of the producer, shall consist of Producer's Note and Supplemental Loan Agreement, secured by a Commodity Chattel Mortgage, and such

other forms and documents as may be prescribed by CCC. Notes and chattel mortgages must have State and documentary revenue stamps affixed thereto where required by law. Loan documents executed by an administrator, executor or trustee will be acceptable only where legally valid.

(b) *New note required.* Where required by State law, or when commodities covered by two or more loans are commingled under the provisions of § 1421.3454, a new Producer's Note and a new Chattel Mortgage shall be completed when a farm-storage loan is extended. Where new forms are not completed, extension of farm-storage loans shall not affect the rights of CCC, including its right to accelerate the maturity date of the note, and the rights and responsibilities of the producer as set forth in this subpart and in the original approved forms completed by the producer.

§ 1421.3456 Quantity eligible for reseal.

The quantity of the commodity eligible for reseal shall be the quantity shown on the original note and chattel mortgage less (a) any quantity delivered not including the quantity represented by over-delivery for which overrun payment is made and (b) the quantity redeemed.

§ 1421.3457 Storage payment.

(a) *Storage payment for 1963–64 reseal period.* (1) A producer who extends his reseal loan for the 1964–65 reseal period will at the time of such extension receive a payment for storage earned during the 1963–64 reseal loan period. This payment will be disbursed by the ASCS county office and will be 14 cents per bushel less any storage payment previously received by the producer from CCC for the 1963–64 storage period.

(2) Upon delivery of the commodity to CCC, the actual quantity of such commodity held in farm-storage under the extended reseal loan will be determined by weighing. The storage payment earned by the producer covering the 1961–62, 1962–63 and the 1963–64 reseal periods will then be recomputed on the basis of the actual quantity determined to have been covered by the extended reseal loan. Any amount due the producer for such storage on the quantity of the eligible commodity delivered in excess of the quantity stated in the extended reseal loan documents will be credited to the producer's account in settlement of the loan. The amount of any over-payment which is determined to have been made to the producer shall be collected from the producer.

(3) No storage payment will be made for the 1963–64 reseal period (i) where the producer has made any false representation in the loan documents or in obtaining the loan, or in deliveries or settlement of the loan, (ii) where during or prior to the 1963–64 reseal period, the commodity has been abandoned or the commodity was damaged or otherwise impaired due to negligence on the part of the producer, or (iii) where during or prior to the 1963–64 reseal period the commodity was converted by the producer or at any time subsequent thereto there was conversion of the commodity by the producer with intent to defraud CCC.

(b) *Full storage payments for 1964–65 reseal period.* A storage payment of 14 cents per bushel will be made to the producer if he redeems the commodity from loan or delivers the commodity under loan on or after July 31, 1965, for corn and March 31, 1965, for wheat. Such dates are referred to in this section as "the maturity date for full storage payments."

(c) *Prorated storage payment*—(1) *Early deliveries and CCC assumed losses.* (i) In the case of deliveries earlier than the maturity date for full storage payments, a storage payment will be computed beginning 60 days subsequent to April 1, 1964 for wheat and August 1, 1964 for corn and ending on the earlier of the date delivery is completed or the date specified for delivery by the county office.

(ii) In case of losses assumed by CCC the storage payment will be computed for the period beginning on the date as set forth in subdivision (i) of this subparagraph and ending on the date the loss occurs.

(iii) The daily rate for these computations shall be $0.00046 per bushel, but shall not exceed in the aggregate 14 cents per bushel. (2) *Redemptions prior to maturity.* On redemptions prior to the maturity date for full storage payments, a storage payment will be made to the producer. Such storage payment will be determined according to the length of time the commodity was in store for the period beginning April 1, 1964, for wheat and August 1, 1964 for corn and ending on the date of repayment. The prorated payment will be computed at the daily rate of $0.00038 but not to exceed in the aggregate 14 cents per bushel.

(d) *Quantity eligible.* Except in the case of partial loans, the quantity eligible for storage payment under paragraphs (a) and (b) of this section shall be (1) in the case of delivery to CCC, or losses assumed by CCC the entire quantity in the bin, (2) in the case of redemptions, the quantity in the bin but not to exceed the measured quantity adjusted for test weight. The quantity eligible for a storage payment in the case of a partial loan shall not exceed the quantity under loan.

(e) *No storage payments.* Notwithstanding the provision of this paragraph, in no case will any storage payment be made for the 1964–65 reseal period where the producer has made any false representation in the loan documents, in obtaining the loan, or in settlement of the loan, where the commodity has been abandoned, where there has been conversion on the part of the producer, or where the commodity was damaged or otherwise impaired due to negligence on the part of the producer.

§ 1421.3458 Maturity.

Loans will mature on demand but not later than March 31, 1965 for wheat and July 31, 1965 for corn.

§ 1421.3459 Death, incompetency, or disappearance.

In the case of the death, incompetency or disappearance of any producer who is entitled to the payment of any sum under the loan, the payment of such sum shall be made to the person or persons who would be entitled to such producer's payment under the regulations contained in §§ 1472.1151 to 1472.1154 of this chapter (Payment Program for Shorn Wool and Unshorn Lambs, 27 F.R. 933, February 1, 1962, as amended), upon proper application to the office of the county committee which made the loan. Application forms may be obtained from the office of the county committee.

§ 1421.3460 Delegation of authority.

No delegation herein to a State or county committee shall preclude the Executive Vice President, CCC, or his designee, from determining any question arising under the program or from reversing or modifying any determination made by a State or county committee, or ASCS commodity office or the ASCS Data Processing Center.

§ 1421.3461 Fraud in settlement of loans.

The making of any fraudulent representation by the producer, in connection with settlement or deliveries under the loan shall render the producer personally liable, aside from any additional liability under criminal and civil frauds statutes, for the amount of the loan, for any additional amounts paid to the producer in the commodity, and for all costs which the Corporation would not have incurred had it not been for the producer's fraudulent representation, together with interest at the rate of 6 percent per annum on such amounts from the date of disbursement. For the purpose of establishing any deficiency remaining due in the event the producer has made any such fraudulent representation, the value of the commodity delivered to the Corporation under the loan or removed by the Corporation, shall be the market value, as determined by the Corporation, on the date of delivery or removal, or the sales price if the commodity is sold by CCC in order to determine its market value.

Effective date. Upon publication in the FEDERAL REGISTER.

Signed in Washington, D.C., on June 15, 1964.

RAY FITZGERALD,
Acting Executive Vice President, Commodity Credit Corporation.

[F.R. Doc. 64–6061; Filed, June 18, 1964; 8:45 a.m.]

Title 32—NATIONAL DEFENSE

Chapter VII—Department of the Air Force

SUBCHAPTER A—AID OF CIVIL AUTHORITIES AND PUBLIC RELATIONS

PART 805—SAFEGUARDING CLASSIFIED INFORMATION

Present Part 805 is deleted and a new Part 805 is inserted as follows:

Sec.
805.1 Dissemination.
805.2 Industrial security program.
805.3 Assignment of classification.
805.4 Declassification for public release.
805.5 Espionage law notation.
805.6 Authorized dissemination.

Sec.

AUTHORITY: The provisions of this Part 805 issued under sec. 8012, 70A Stat. 488; 10 U.S.C. 8012.

SOURCE: AFR 205–1, November 1, 1963.

§ 805.1 Dissemination.

Requirement for access: Knowledge or possession of classified information is permitted only to persons who need it to do their job. No one has a right to classified information solely by virtue of his rank or position. The responsibility for determining whether or not a person's duties require access to classified information rests with the official having custody of the classified material. This requirement applies to all classified information.

§ 805.2 Industrial security program.

To be effective, the security program must provide protection for classified information entrusted to contractors as well as that held only by the Government. Therefore, an information security system and program have been established by the Department of Defense to safeguard classified information entrusted to DoD contractors and their employees. The Industrial Security Program, given effect by the execution of a Security Agreement between DoD and the contractor, establishes security requirements and access authorization procedures which are similar to those that apply in the Air Force, but which have been adapted to the operating requirements of industry, educational institutions, research activities, and consultants. The security procedures that contractors must follow are set forth in the DoD Industrial Security Manual for Safeguarding Classified Information (ISM); and the security and procurement responsibilities of the Air Force in relation to the DoD Industrial Security Program are set forth in AFR 205–4 (Armed Forces Industrial Security Regulations) and supplemented in this part. Familiarity with those provisions is required any time a procurement action is proposed or undertaken which involves the release of classified information to a contractor or his employees, which requires the contractor or his employees to have access to classified information, or which will result in developing or producing information or material that will be assigned a classification.

§ 805.3 Assignment of classification.

The provisions of Executive Order 10501, as implemented in the DoD directives and this part, apply only to official information of the United States Government and do not extend to privately-owned information. Therefore, the assignment of a defense classification to privately-owned information is not authorized. Normally, AFR 11–30 (Custody, Use and Preservation of DoD Official Information Which Requires Protection in the Public Interest) provides the means for withholding from public release privately-owned information entrusted to the Air Force when its release would be contrary to the public interest. However, the Patent Secrecy Act of 1952 (35 U.S.C. 181–188) provides one means whereby the Government can enjoin the public release of privately-owned information (see § 805.12).

§ 805.4 Declassification for public release.

Release by the office of primary responsibility: only Classified information approved for public release must be declassified before it is released. Persons who cancel or approve the cancellation of the classification or information, and simultaneously approve its release to the public, must take action to notify each addressee to whom he transmitted the material, regarding change or cancellation of classification, as soon as possible. When the release involves a weapon system for which a System Program Office has been established, the command having primary system management responsibility must also be notified. The issuance of timely declassification notices is necessary to preserve the effectiveness and integrity of the security classification system, and to conserve Air Force resources.

§ 805.5 Espionage law notation.

A classified document furnished to a DoD contractor, or to any other person or activity outside the Executive Branch, shall bear the following additional notation at least once:

> This material contains information affecting the national defense of the United States within the meaning of the Espionage Laws (Title 18, U.S.C., sections 793 and 794), the transmission or revelation of which in any manner to an unauthorized person is prohibited by law.

§ 805.6 Authorized dissemination.

(a) (1) *DoD contractors.* Persons and other legal entities, such as educational, scientific, and industrial organizations, may be authorized access to classified information if it is required for the negotiation or performance of a DoD contract and they have been determined to be trustworthy pursuant to AFR 205–4.

(2) *Other persons and entities.* Persons and legal entities, other than those described in subparagraph (1) of this paragraph, may be authorized access to classified information only if they must have it to perform a function which, in the judgment of the releasing official, will be in the interest of promoting national defense; they have been determined to be trustworthy; and they can and will protect the information adequately. These provisions apply to educational, scientific, and industrial organizations not acting in the capacity of DoD contractors; to officials and agencies of a State or of a Federal agency not part of the Executive Branch; and to private persons.

NOTE: For any purpose not stated in subparagraph (2) of this paragraph, problems involving dissemination to private persons or activities should be solved by declassification, rather than by expanding authorized access to classified matter.

(b) *Non-DoD information.* Classified information possessed by the Department of Defense but originated by another Federal department or agency shall be disseminated outside DoD only with the consent of the originating agency. The one exception to this rule is provided by section 102, National Security Act of July 26, 1947 (50 U.S.C. 403), which authorizes the Director of Central Intelligence to correlate and to evaluate intelligence relating to the national security, and to provide for the appropriate dissemination thereof within the Government.

NOTE: A contracting agency possesses a proprietary interest in information originated in connection with one of its contracts. Therefore, for classification and dissemination purposes, information originated by a contractor in connection with a Government contract is considered to have been originated by the contracting Government department or agency.

§ 805.7 Determining requirement for access.

(a) *Policy.* Knowledge or possession of classified information is permitted only to persons to whom the information is essential in order to perform their duties in the interest of national security. No one has a right to have access to classified information solely by virtue of his rank or position; if a person does not need the information to perform his officially assigned duties, he shall not be given access to it.

(b) *Applicability.* The prerequisites for dissemination, and the authority to disseminate, vary according to the status of the intended recipient. A person or organization can, and frequently does, have more than one status; for example:

(1) One person can be a Reserve officer, a Government employee, and a private citizen, and

(2) An organization or person can be a contractor or consultant to the Government, and a contractor to a nongovernmental enterprise. In all such cases, the following rules apply:

(i) Before approving a release of classified information, the releasing official must determine the status or capacity in which the intended recipient is acting in connection with each proposed release or dissemination of classified information.

(ii) The basis for dissemination, and the authority to approve it, as provided in §§ 805.6 through 805.10, vary according to the intended recipient's status in relation to the proposed release. Thus, for example, if the recipient is acting in the capacity of a DoD contractor, §§ 805.6(a)(1) and 805.9(f) would apply; if the same recipient is acting in a private capacity, §§ 805.6(a)(2) and 805.9(h) would apply.

§ 805.8 Dissemination for personal or private use.

Classified information shall not be released for private use (personal or commercial, or as background material). Any person who requests classified information for such use is considered a "private individual." His request shall not be approved even though he may have been partly or solely responsible for production of the information. This rule applies to requests from military personnel on active duty or in retired status, members of the Reserve Forces, and civilian officials, as well as other individuals.

§ 805.9 Dissemination and disclosure authority.

(a) *To other U.S. Government personnel and agencies.* Unless otherwise provided in §§ 805.6 through 805.10, designated officials are authorized to make or to approve dissemination to other departments, agencies, branches, and personnel of the U.S. Government. Each such release shall be made through the normal channels of communication established between the Air Force and the department or agency concerned, and the release shall be reviewed for propriety and desirability at each intervening Air Force element.

(b) *To Congress.* All requests by the Congress or its committees or members for classified information will be referred to the Secretary of the Air Force (Director of Legislative Liaison, SAFLL) according to AFR 11–7 (Air Force Relations with Congress).

(c) *To General Accounting Office (GAO).* Authority and procedures for disclosing classified information to GAO representatives are prescribed in AFR 11–8 (Air Force Relations with the General Accounting Office).

(d) *For litigation purposes.* Requests or subpoenas for the appearance of witnesses before civil tribunals or for classified information to be used in connection with litigation will be acted upon as directed in §§ 804.401 through 804.410 of this subchapter.

(e) *To the Renegotiation Board.* By agreement between the Department of Defense and the Renegotiation Board, certain appropriately cleared and specifically designated personnel of the Renegotiation Board are authorized to have access to DoD classified information, provided such access is necessary in connection with the official functions of the Renegotiation Board. Lists of Renegotiation Board personnel certified to the Department of Defense for such access are revised at least annually, and are distributed to major air commands concerned. Inquiries about these provisions or lists should be sent through channels to Hq USAF (AFISL–3), Washington, D.C., 20333.

NOTE: The functions of the Renegotiation Board are specified in the Renegotiation Act of 1951 (Public Law 9, 82d Congress); in addition, certain powers, functions, and duties of the Secretary of Defense are delegated to the Renegotiation Board by DoD Directive 4105.16.

(f) *For procurement, research, and development purposes*—(1) *General limitations.* Knowledge or access to classified information shall be permitted to bidders, contractors, or grantees only when it is essential to the accomplishment of a function which is necessary in the interest of promoting the national defense.

(2) *Dissemination authority.* The major air command responsible for the negotiation, award, or administration of a contract for the procurement of materiel, supplies, or services is authorized to disseminate the classified information and material which is essential to the performance of the contract. The major air command having responsibility for the project involved in a procurement action is also authorized to disseminate classified information and material which is essential to the performance of the project. In addition, the Commanders, Air Force Systems Command and Office of Aerospace Research, are authorized to disseminate classified information and material to the extent necessary for the successful fulfillment of the objectives of the grantee and long-range planning program. The Commander, Defense Documentation Center, is authorized to disseminate classified information and material to the extent provided in DoD Directive 5100.36, provided the need for the information in a specific field of interest has been certified by the contracting officer or project office concerned.

(3) *Safeguarding requirements.* Classified information and material disseminated according to subparagraph (2) of this paragraph shall be permitted only to persons or activities participating in the DoD Industrial Security Program as the result of the negotiation of a DoD Security Agreement (DD Form 441). Prior to dissemination, it must be ascertained (according to AFR 205–4) that the proposed recipient has an appropriate and current facility security clearance and the capability to safeguard the classified material. (See §§ 805.16 through 805.25 for further details on the industrial security program.)

(g) *To foreign nationals.* Classified defense information will not be furnished or disclosed to any foreign national except as stated in this paragraph:

(1) *Foreign governments and their representatives.* The Assistant Chief of Staff, Intelligence, Hq USAF, is responsible for developing and implementing Air Force policy relating to the disclosure of classified defense information to foreign governments and international organizations. Pertinent instructions are contained in AFR 200–9 and AF–DCMI 1956 (Department of the Air Force document, Disclosure of Classified Military Information to Foreign Governments).

(i) Orders or written instructions which attach foreign nationals to installations or permit them to visit installations or contractors will: (*a*) Authorize their access to military information, and (*b*) specifically identify the classification category and subject matter of any classified information that may be disclosed. Commanders and chiefs of offices must restrict access to military information by foreign nationals to that specifically authorized.

(ii) When release of classified material is authorized, the method of transmitting classified material to a foreign government or to its designated representative must be one that is authorized by this part. In addition, and regardless of the classification category of the information, a receipt shall be obtained; the Receipt for Documents Released to Accredited Representatives of Foreign Nations (AF Form 349) shall be used for this purpose.

(2) *Foreign contractors.* See § 805.21.

(3) *Foreign national employees of the Air Force.* See AFR 205–10 (Security Policy on the Use of Non-U.S. National Employees).

(4) *Foreign national employees of contractors.* See AFR 205–6 (Personnel Investigations, Security Clearances and Access Authorizations).

(5) *Other foreign nationals.* These provisions apply to foreign nationals other than those described in subparagraphs (1) through (4) of this paragraph. The disclosure of classified information to foreign nationals or foreign organizations acting in a private (i.e., nongovernmental) capacity is not authorized. Requests from, or proposals to disclose classified information to such individuals or organizations shall be sent through normal command channels to Hq USAF (AFNICBB), Washington, D.C., 20330, for action or disposition.

NOTE: When appropriate in the interest of promoting national defense, AFNIN will initiate action so that the prospective recipient is officially sponsored by his government, whereupon the provisions of subparagraph (1) of this paragraph will apply.

(6) *Reports of disclosures to foreign visitors.* When a visit report is specifically requested by Hq USAF, commanders shall send through channels to Hq USAF (AFNICBB) a report on foreign nationals who visit their installations and who have access to classified information under Air Force control or jurisdiction. Similarly, when a foreign national visits a contractor's facility and has access to Air Force classified information pursuant to paragraph 3–103*h*, AFR 205–4, and 28*h*, ISM, the cognizant security office shall, when a visit is requested, obtain the necessary information from the contrac-

tor and forward a report through channels to Hq USAF (AFNICBB). The major air command that indorses the report shall review it for completeness and accuracy, and shall determine whether the disclosures were within the policy referred to in subparagraph (1) of this paragraph. When requested, a similar report shall be submitted by chiefs of Hq USAF offices on the directorate and higher levels regarding visits by foreign nationals to their offices. Reports must reach Hq USAF within 20 days after the completion of the visit. Each report will include:

(i) Name, official position, and nationality of each visitor.

(ii) Specific authority for visit. (If the visit was authorized by Hq USAF, the USAF authorization number will be quoted; if authorized by a major air commander, quote the specific authority upon which the commander's action was based.)

(iii) A brief of what was shown, discussed, explained, and refused.

(iv) Highest classification of the information authorized for disclosure, and the highest classification of the information disclosed.

(v) Any remarks the reporting officer believes of importance in the final evaluation of the report.

(h) *For historical research.* All requests by persons outside the Executive Branch of the Government for access to classified information required in connection with historical research projects shall be forwarded through channels to the Office of Information (SAF–OI), OSAF, Washington, D.C., 20330, for action.

§ 805.10 Visits to Air Force installations and activities.

(a) *Restrictions on movements of visitors.* To protect classified information, the commander must restrict the movement of visitors entering his installation. Visitors authorized to have access to classified matter will be accompanied by the commander, or his representative, who has been informed of the restrictions placed upon the visitor.

(b) *Visits by DoD contractor personnel.* Requests for visit approval are prepared by DoD contractors and their personnel in accordance with the DoD Industrial Security Manual.

(c) *Visits by other personnel.* Requests for the approval of a visit involving access to classified information shall be submitted early enough to allow time for consideration, decision, and reply by the approving authority. The requests shall include the following information, as applicable:

(1) Name in full, grade, title, position.

(2) Nationality of visitor (immigrant aliens will furnish alien registration number), date, and place of birth.

(3) Current residence or military assignment.

(4) Employer or sponsor.

(5) Name and location of installation or activity to be visited.

(6) Date, time, and duration of visit.

(7) Purpose of visit, in detail.

(8) Level of classified access authorized and name of authority granting access authorization (if clearance has previously been granted).

§ 805.11 General rules for safeguarding.

(a) *Location of meetings.* Because of the security hazards inherent in the use of any normally-public meeting place for the presentation or discussion of classified information, classified meetings or classified sessions of a meeting shall, whenever possible, be held only on a U.S. Government installation or at a cleared facility of a DoD contractor. The only exception that may be made to this rule is a meeting at which information classified no higher than Confidential is to be disclosed or discussed may be held at other locations provided: (1) An adequate U.S. Government installation or a cleared DoD contractor facility is not available, and (2) it has been specifically authorized in writing at numbered air force or comparable or higher level.

(b) *Attendance by foreign nationals.* The following provisions apply only to meetings in which classified information is to be discussed or disclosed at one session or more.

(1) Foreign nationals of countries outside the Sino-Soviet Bloc may be approved for attendance at an Air Force conducted meeting provided such attendance is individually and specifically authorized in accordance with § 805.9 (g) (1).

(2) Representatives of Sino-Soviet Bloc countries shall not normally be authorized to attend any session, or any other portion, of a meeting conducted by an Air Force activity. However, when the attendance of such individuals at an unclassified session appears to be desirable, a request for approval of such attendance shall be submitted through channels to Hq USAF (AFNICB), where action will be taken in accordance with DoD Directive 5200.12. Such requests shall include: the names of the individuals, the dates on which attendance is desired, the subject matter scheduled for presentation, the location of the meeting, and the subject titles of scientific, technical, or other papers scheduled for presentation by foreign nationals. In any case, those so approved shall be excluded without exception from all classified sessions, presentations, and displays.

(c) *Individual activities.* Military and civilian personnel shall not include classified information in any personal or commercial article, presentation, thesis, book, or other product written for commercial publication or public distribution.

(d) *Use to preclude inadvertent disclosure.* If the sender or the recipient of a classified document determines that its anticipated handling or distribution renders it liable to inadvertent disclosure to a foreign national at a given unit or location, he shall apply the special handling notice described in paragraph (e) of this section. (The need for this would arise when a classified document is sent to a headquarters or unit to which foreign nationals are assigned or attached, or when it is sent to the U.S. element of an international pact headquarters or organization.)

(e) *Special handling notice.* When a determination is made, it shall be annotated appropriately to reflect that decision. The abbreviation "NOFORN" may be used when appropriate. In other cases, the following special handling notice shall be used:

> SPECIAL HANDLING REQUIRED
>
> NOT RELEASABLE TO FOREIGN NATIONALS
>
> The information contained in this document will not be disclosed to foreign nationals or their representatives.

§ 805.12 Patent Secrecy Act.

The Patent Secrecy Act of 1952 (35 U.S.C. 181–188) provides that if, in the opinion of the Atomic Energy Commission, the Secretary of Defense, or the head of another designated Executive department or agency, the publication or disclosure of an invention by the granting of a patent therefor would be detrimental to the national security, the Commissioner of Patents shall order that the invention be kept secret and shall withhold the grant of a patent for such period as the national interest requires, and shall so notify the applicant. DoD Directive 5535.2 delegates to the Secretaries of the Army, Navy, and Air Force the authority to make such determinations on behalf of the Secretary of Defense. Patent applications on which secrecy orders have been imposed, and the substance of the information they contain, shall be handled in the Air Force as follows:

(a) *Official information.* A defense classification can be assigned only to official information. If a patent application contains official information which requires protection under Executive Order 10501, the information shall be assigned a defense classification. In this case, the document shall be marked and safeguarded as prescribed by this part for its assigned classification, with special attention given to the requirements for marking individual paragraphs.

(b) *Private information.* If the patent application does not contain official information, the following procedures shall be uesd:

(1) The information shall be withheld from public release; its dissemination within the Air Force shall be severely limited; and the applicant shall be instructed not to disclose it to any unauthorized person. Documents containing the information shall be afforded secure storage, and the document shall be transmitted, if transmission is necessary, in double covers by U.S. Registered or Certified mail.

(2) Ordinarily, the document need not be marked in any way. However, when it is necessary or desirable to inform or to warn the intended recipient that the information is the subject of a secrecy order issued pursuant to the Act of 1952, instructions should be included in a covering letter of transmittal substantially as follows:

The attached material contains information relating to a patent application on

which secrecy orders have been issued by the U.S. Patent Office after determination that its publication or disclosure would be detrimental to the national security. See the Patent Secrecy Act of 1952, 35 U.S.C. 181–188.

In view of the determination, the attached material affects the national defense within the meaning of the espionage laws (18 U.S.C. 793–794). Its transmission or revelation in any manner to an unauthorized person is prohibited by law.

When necessary, however, documents and material containing the information in the patent application may also be marked with a shorter notice as follows:

> Withheld under the Patent Secrecy Act of 1952 (35 U.S.C. 181–188)

(c) *Foreign registration.* When a patent application, on which secrecy orders have been issued, is approved for registration with a foreign government under the provisions of the Act of 1952 and agreements on the interchange of patent rights and technical information for defense purposes, additional considerations are involved. In such cases, action must be taken to invoke the protection of the foreign government's national security system. Therefore, the copies of the patent application prepared for foreign registration (but only those copies) shall be marked on the bottom of each page with a notation specifying the degree of protection (Secret or Confidential) as determined by the Armed Services Patent Advisory Board. For example:

> Withheld under the Patent Secrecy Act of 1952 (35 U.S.C. 181–188). Handle as:
>
> SECRET

§ 805.13 Transportation of classified material.

(a) *Shipments protected by Government or contractor escort via commercial carrier within the United States.* Top Secret, Secret, or Confidential material may be shipped within the continental U.S., and within (but not between) Alaska, Hawaii, a U.S. possession, or the Commonwealth of Puerto Rico, by any commercial carrier that is approved by the appropriate regulatory authority (e.g., I.C.C., C.A.B., etc.) or by the appropriate military commander within the Commonwealth of Puerto Rico or a U.S. possession, provided:

(1) For shipments made by an Air Force contractor or subcontractor, the classified material is kept under the continuous protection of appropriately cleared military or civil service personnel or, when specifically authorized by the Air Force contracting officer, the continuous protection of appropriately cleared employees of the contractor or subcontractor involved.

(b) *Shipments protected by commercial carrier in the United States*—(1) *Limitation on categories and types.* Top Secret material, registered cryptomaterial, and certain Atomic Energy Restricted Data shall not be shipped by commercial carrier without being protected by an authorized courier, and by guards if necessary. Other Secret and Confidential material may be shipped wholly within the continental U.S., Hawaii, Alaska, the Commonwealth of Puerto Rico, or a U.S. possession, as provided in paragraphs (c) through (e) of this section, without U.S. Government or contractor escort.

(c) *Air carriers.* (1) Confidential material may be shipped by commercial airline under these conditions:

(i) Hand-to-hand receipting is required from the time the shipment leaves the hands of the consignor until delivered to the consignee; and

(ii) The airline must provide constant security measures to protect the material (including periods that the material is in flight, grounded in transit, awaiting transit, and awaiting pickup by, or delivery to, consignee). Commanders must make advance arrangements to make sure that the carrier is informed of the necessary protection and agrees in writing to provide it. However, such bilateral arrangements need not be made when a shipment is routed via a carrier referred to in subparagraph (2) of this paragraph.

(2) The Rule 6.10 commercial air carrier signature service referred to in AFM 75–1, which is provided only by certain participating commercial airlines, meets the security requirements necessary for the shipment of Confidential material. While the shipments in subparagraph (1) of this paragraph may not be transferred by one airline to any other carrier, consignors may route a shipment of Confidential material via more than one airline participating in the Rule 6.10 service.

(d) *Motor carrier.* Confidential material may be shipped by commercial truck, including a tractor-trailer combination, or by commercial bus, subject to the following:

(1) The carrier shall be required to have his employees protect the shipment constantly. Security measures must include continuous direct surveillance over the shipment, over the vehicle, or over any storage facility that is used.

(2) The material involved shall be prepared for shipment so as to protect classified information from view.

(e) *Railway freight.* Confidential material may be shipped by railway frieght either in a closed car or on an open car. Prepare the material for shipment so as to protect classified information from view. If an open car is used, shipping containers and uncrated materiel must be suitably locked or sealed to the car.

NOTE: External features of classified materiel that do not reveal classified information need not be covered, provided the materiel is always under proper supervision and control to prevent unauthorized access to or disclosure of the classified internal features.

§ 805.14 Precluding unauthorized inspection or access to classified shipments by State authorities.

(a) *General.* Within the United States and its territories and possessions, the transportation or shipment of classified material by or for the Federal Government, and the protection of such classified material while in transit, constitute a Federal function. As such, the function is exempt from control or unreasonable interference by representatives of State or local governments (hereafter referred to, for convenience, as "State authorities"). In performing this function, the Federal Government may act through its own agents, officers, enlisted personnel, or employees, using its own vehicles and equipment; or it may act through a contractor and contractor employees, including a commercial carrier. Regardless of the means used, it remains a Federal function and, although the technical rules applicable in each instance may vary, the practical effect remains the same: unless authorized by the Federal Government, officers or agencies of a State may not lawfully search or inspect shipments of classified material transported by or on behalf of the Federal Government.

(b) *Extent and limitations on the immunity and rights of personnel accompanying classified shipments.* (1) Any person (military, civil service employee, or contractor employee) properly detailed to guard, or to guard and transport, a shipment of classified material has the legal right and responsibility to protect such material from inspection or access by any and all unauthorized persons, including State authorities and their officers or employees. In his protecting and securing of such classified material, he may use such force at his command as is reasonable to a prudent man under the circumstances.

(2) The foregoing would not preclude an authorized representative of the Federal Government from making an otherwise lawful search (although by interdepartmental agreements they usually refrain from such searches). Further, the immunity from search or inspection by State authorities does not preclude State agents from stopping and, in appropriate instances, arresting drivers and other attending personnel for misconduct or other violations of State law arising through acts in excess of their authority or not a part of their official duties.

(c) *Rules governing shipments.* To some extent, the technical rules applicable to various shipments of classified material will differ, depending on whether shipment is being effected by Government vehicle or by a commercial carrier or other contractor.

(1) Shipment by Government vehicle: The shipment of classified material by military or civil service personnel in a Government vehicle is a function which carries all of the Federal sovereign immunities outlined in paragraphs (a) and (b) of this section.

(2) Shipment by commercial carrier or contractor: Generally, commercial carriers or contractors do not have the sovereign immunities of the Federal Government as such. Thus, within limits, a State may regulate and control the activities of contractors and commercial carriers operating within its boundaries. However, the extent to which State authorities may regulate or control a commercial carrier or contractor transporting classified material is limited to that which would not unreasonably impede or defeat the purpose of the contract with the Government.

Thus, for example, a State may properly require compliance with vehicle licensing laws, vehicle automotive inspection laws, drivers' licensing laws, vehicle weight laws, and other requirements for the operation and maintenance of vehicles on public roads. However, where a contractor or commercial carrier has been employed by the Federal Government to transport and keep secure classified material, a State does not have a legal right to search or inspect such classified shipments if the effect would be to subject the classified material to compromise, as the security of the classified material is the very essence of the performance required by the Federal Government. In such instances, therefore, the carrier or contractor is under no legal obligation to submit the classified material to search or inspection by State authorities, but he has the legal right and responsibility as the agent of the Federal Government to protect and secure the classified material in his custody.

(3) Use of firearms: Guard and escort personnel are never required by this part to bear firearms for the protection of classified information, nor should they be required to bear arms solely for that purpose. However, when required for reasons other than the protection of classified information, or when the responsible commander deems it necessary, he may require the use of armed guards for the protection of material under his jurisdiction. Military and civil service personnel are authorized to be armed as deemed necessary without regard to State laws concerning weapons, so long as the individual remains within the scope of his orders on wearing and using arms. Such personnel, however, must comply with the provisions of Federal law when applicable. Commercial carrier personnel and contractor personnel bearing arms in the accomplishment of the shipment of classified material do so under the authority and control of both State and Federal laws which apply. The commercial carrier or contractor is responsible for arranging any necessary permits in this regard.

(d) *Instructions for personnel accompanying classified shipments*—(1) Commanders responsible for the shipment of classified material shall insure that personnel accompanying each shipment are properly instructed concerning their rights and responsibilities in the protection of that shipment. In particular, such personnel shall be advised that, in dealing with State authorities, the display or use of arms or physical force should be avoided if at all possible short of compromising the classified material. State and local governments have as great and as patriotic an interest in the national defense as the Federal Government; therefore, in most instances, classified shipments can be protected from unauthorized access, search, or inspection by State authorities if the personnel accompanying the shipment explain the nature of the shipment to the State representatives, exercise good judgment and common-sense, and produce proper identification. When necessary, however, personnel accompanying the shipment should call for assistance from the nearest military agency, and should the need arise, they may relinquish custody of the shipment to representatives of the nearest U.S. military agency or to representatives of any other appropriate Federal agency.

(2) Instructions to personnel accompanying shipments of classified material shall be in written form, and shall include, in addition to the requirements of subparagraph (1) of this paragraph: (i) Provisions for contacting the nearest military establishment if the classified shipment is detained for any reason; (ii) provisions for insuring the maintenance of custody and the prevention of compromise of the classified material in the event of accident, arrest arising from a violation of State law, or other comparable situations; and (iii) a formal notice for presentation to any person or agency attempting to interfere with the shipment, reading substantially as follows:

> You are hereby placed on notice that this is a classified shipment by the Federal Government, and that this shipment is immune and exempt from search or inspection by any unauthorized persons, including State authorities.
>
> The notice must be prepared to show its official nature, origin, applicability, and duration. This shall be accomplished by: preparing the notice on official letterhead stationery signed by the commander responsible for the shipment (or his designee), and bearing the organizational seal if one is available; specifying in the notice the shipment or transaction to which it applies; stating the approximate inclusive dates of the shipment or transaction; and invalidating the notice on the terminal date of the shipment.

NOTE: In the case of classified shipments containing explosives or other dangerous articles, the instructions in this section apply in addition to those prescribed in chapter 216, AFM 75–2 (Military Traffic Management Regulation). In case of accident, fire, or comparable situations involving classified shipments of explosives or other dangerous articles, the interest of the public safety shall transcend the responsibility to preclude access, thereby permitting access by firefighting, demolition, or other emergency personnel as necessary.

§ 805.15 Visits to DoD contractor facilities.

Visits to DoD contractors involving access to Restricted Data in their custody shall be processed as prescribed in AFR 205–4 unless the DoD contractor is also an Atomic Energy Commission contractor. In the latter case, if the visit would also involve access to the Restricted Data pertaining to the AEC contract, the prescribed access and visit procedures shall apply.

§ 805.16 Industrial Security Manual.

The Industrial Security Manual for Safeguarding Classified Information (ISM) is a Department of Defense publication which contains detailed security rules for bidders and contractors in the United States, including firms in the United States which perform classified contract work in foreign locations. The manual is made applicable to a bidder by execution of the Department of Defense Security Agreement (DD Form 441), and to a contractor by including a security requirements clause in the contract.

§ 805.17 Contracting and security responsibility.

(a) *Retention and recovery of classified material.* (1) The contracting officer is responsible for prompt, positive action to recover all classified material released or produced in connection with a bid, proposal, or contract, except that which has been destroyed in accordance with paragraph 14, ISM, or that which the contractor has specifically been authorized to retain pursuant to paragraph 5k, ISM. The PCO is responsible for this action in the case of a bid or proposal. The ACO is responsible for the action upon the completion or termination of a contract.

(2) When a contracting officer authorizes a contractor to retain classified material under the authority given in paragraph 5k, ISM, he shall furnish a list or description of the material and a copy of the authorization to the cognizant security office concerned. In addition, when he authorizes such retention, the contracting officer retains a residual responsibility, in accordance with paragraph 1–308, AFR 205–4, for appropriate classification actions in regard to the classified information involved, and for recovering the material at the end of the authorized retention period. This responsibility continues until the classified information has been destroyed, declassified, or recovered in accordance with subparagraph (1) of this section.

§ 805.18 Facility clearances and personnel access authorizations.

(a) *Facility security clearances.* A facility security clearance is an administrative determination that a facility is eligible, from a security viewpoint, for access to classified information of the same or lower category as the clearance granted. Classified information may be disclosed only to organizations which have executed a DoD Security Agreement (DD Form 441) and which have been granted a facility security clearance. A facility security clearance may be granted to meet (1) a Government need, or (2) the need of a Government contractor who intends to negotiate a classified subcontract. When a PCO has a requirement to enter into precontract negotiations involving the disclosure of classified information, or to award a classified contract, he shall submit to the appropriate cognizant security office a request for the issuance of a facility security clearance. The ACO shall take similar action when a contractor has a requirement to enter into precontract negotiations with a subcontractor involving the disclosure of classified information, or to award a classified subcontract. In addition, when the PCO is aware of a future classified procurement need, and believes that undesirable delays will result if he waits until he is ready to start precontract negotiations before initiating facility security clearance action, he may submit the request for a clearance of any facility that is

capable of and interested in filling that procurement need.

(b) *Granting facility security clearances.* Only those facilities located in the 50 States, the District of Columbia, U.S. possessions, or Puerto Rico may be granted facility security clearances.

(c) *Personnel access authorizations.* Contractor personnel requiring access to classified defense information may be granted access authorizations in accordance with the instructions contained in AFR 205–6. That regulation also contains instructions on the suspension, denial, or revocation of access authorizations for contractor personnel.

§ 805.19 Contracts performed on installations.

(a) The Air Force Procurement Instruction requires that each classified contract contain as a minimum a security clause requiring the contractor to apply the principles of his Security Agreement (DD Form 441) for the purpose of safeguarding classified information. The contractor is bound by this requirement regardless of where the contract is performed. However, security matters pertaining to Air Force installations are not governed by the ISM or AFR 205–4. Therefore, the following instructions apply to classified contracts which require performance on Air Force installations. With the exception of paragraph (d) of this section (which applies only to installations located in the United States, U.S. possessions, or Puerto Rico), this section applies to all Air Force activities, world-wide.

(b) Installation security support: When classified contracts are to be performed on an installation, the commander thereof shall normally be required to provide certain security support to the contractor in order to insure effective and economical protection of classified material in possession of the contractor, as well as to insure integration, to the extent appropriate, of the contractor's security operations with those of the installation. The extent and nature of the support to be provided should be determined by agreement between the project command, contracting command, and the installation commander, and may include such items as physical security, storage facilities for classified material, and the use of the installation's facilities for transmission and accounting for classified material.

(c) Security supervision functions: The commander responsible for security supervision shall require the contractor to report to the installation commander any occurrences, incident to the contractor's on-base operation, which involve espionage, sabotage, or subversive activity; or the compromise or suspected compromise of classified information. These reports will be in addition to those the contractor must make to his cognizant security office, pursuant to paragraph 6, ISM.

(d) Limitation on facility security clearances: A facility security clearance will not be granted for contractor operations within an Air Force installation, except when the contractor operation is to be relatively permanent or when the operation is to be autonomous and is not to be integrated with the military operation. When the contractor's on-base operation is not cleared as a separate facility, the contractor must have executed a DoD Security Agreement and have an active facility security clearance for that facility of his organization which is responsible for the contract being performed on the installation. In those instances when a contractor's activity is located on an installation in the U.S., its possessions, or Puerto Rico and is a separate operating entity performing classified contract work of an industrial nature, it may be designated a separate facility.

(e) Visits to installations: Contractor personnel who make visits to Air Force installations in the performance of their duties will be treated as visitors in accordance with AFR 205–4, if they require access to classified information.

(f) Additional security requirements: Necessary security requirements which are additional to or different from those in the ISM must be made effective by including them in, or modifying, the contract pursuant to paragraph 5b, ISM. The specific duties and responsibilities of the contractor and of the installation where the contract is to be performed should be clearly defined (see paragraph (b) of this section). In those instances where the contractor's on-base operation is designated a separate facility (see paragraph (d) of this section), it normally is necessary only to include a special clause requiring compliance by the contractor with the appropriate security directives of the installation. Therefore, contracting officers shall incorporate, as a minimum, the following security requirements clause in any classified contract or subcontract which will require performance on an Air Force installation:

> Notwithstanding any other provision in this contract affecting military security requirements, the contractor shall comply with such modifications or changes in such security requirements as are prescribed in writing by the commander of the Air Force installation at which the work under this contract or any part thereof is being performed. Should any such modifications or changes in security requirements result in an increase or decrease in security costs under this contract, the contract price shall be subject to an equitable adjustment by reason of such increased or decreased costs. Any equitable adjustment shall be accomplished in the same manner as if such modifications or changes were directed under the "Changes" clause in this contract.

§ 805.20 Contracts performed outside the United States.

(a) *Transmission outside the U.S.* (1) If the transmission of classified information to or from a contractor or contractor employee located outside the continental United States is approved pursuant to paragraph 12i, ISM, the material must be addressed to a military authority for delivery to the contractor or his employee. Also the material must be routed through the same channels as are authorized in this part for transmitting classified material in the custody of Air Force units. (Classified material will be transmitted only through U.S. Government channels and under the control of U.S. Government activities. Normally, transmission will be by registered mail through the U.S. military postal services or by the Armed Forces Courier Service.)

(2) When transmission of classified material between oversea locations through normal military or other U.S. Government channels would create unacceptable operational problems, appropriately cleared contractor personnel may be appointed in writing by the ACO, upon approval of the activity responsible for the security supervision of the contract, to act as courier or escort for the material, provided the transmission does not cross national boundaries, is accomplished (begun and completed) during normal daytime duty hours of the same day, and is in accordance with the agreements in effect with the country concerned.

(3) When contract work within a foreign country involves a project of joint interest to the foreign government and the United States, it may be necessary to make special arrangements for transmitting classified information held jointly by the two governments. The phrase "held jointly by the two governments," as used in this section, refers to U.S. classified information which has been released to the foreign government, foreign classified information released to the United States, or classified information developed jointly by the two governments concerned. In such cases, the classified material may be transmitted to the contractor by either government. The procedures for transmission may be those prescribed by this part, or when transmission is within the host country, the procedures authorized by that country may be used. However, the ACO, in collaboration with the project officer, should develop specific procedures which meet the practical requirements of the project while maintaining required standards of security for the information. Such procedures must be coordinated with the activity having security supervisory responsibility for the contractor's oversea operation involved.

(4) If a U.S. contractor engaged in a bilateral project requires access to U.S. classified information which is releaseable under § 805.9(g) (but which has not been approved for release) to the foreign government involved in the bilateral project, the procedures prescribed in this part for transmission of such material normally will be used. In exceptional cases, however, special transmission procedures may be established to meet unique operational requirements. In such cases, the ACO, in conjunction with the project officer and the activity responsible for security supervision of the contractor's activity, may develop appropriate procedures which will meet operational requirements while maintaining the necessary degree of security. The proposed procedure shall be forwarded for approval to Hq USAF (AFISL). The request for approval must include a detailed statement of facts and justification.

(b) *Storage in foreign countries.* (1) The storage of classified defense information in a foreign country within any

location other than a U.S. military installation or other U.S. Government controlled installation is prohibited. Contractor personnel in foreign countries who must be given access to classified material will be advised that it is necessary, in order to assure security, for the material to remain under U.S. Government control. (If storage at a U.S. military installation is not practical, the contracting officer must arrange for storage with a U.S. military attache, Military Assistance Advisory Group (MAAG), or a U.S. diplomatic or consular officer.)

(2) However, if the contract work involves a bilateral project (see paragraph (a)(3) of this section), special arrangements for storing classified information held jointly by the participating governments may be developed. In such cases, the classified material may be retained for the contractor under the custody of that government which has an activity most conveniently located with regard to the contractor's operation. If such procedures are established, the material shall be stored and safeguarded in accordance with the rules of the government accepting responsibility for the material and providing the storage facilities.

§ 805.21 Contracts performed by foreign contractors.

(a) *General.* The major air commander who has a requirement for procuring supplies or services in a foreign country from an individual, company, or other legal entity of that country may initiate procurement action which will involve the release or disclosure of classified defense information, provided:

(1) The classified information involved has been approved for release (or is determined to be releasable) to the government of the foreign country as described in § 805.9(g).

(2) A government-to-government agreement exists or is established between the Unied States and the foreign government whereby the foreign government has obligated itself to assume responsibility for the adequate protection of the classified information involved in or released with the contract.

(3) A government-to-government agreement exists or is established between the United States and the foreign government whereby that government agrees to permit the United States to contract with individuals, companies, or other legal entities under its jurisdiction. Such agreements may permit the United States Government to negotiate directly with the prospective contractor, or they may require the negotiations to be conducted through government-to-government channels.

(b) *Industrial security measures.* The effect of the agreement referred to in paragraph (a)(2) of this section is that the foreign government legally imposes its own "industrial security program" on the contractor in order to protect the United States classified information involved in the contract. The procedures for safeguarding classified information, the clearance of the contractor and his employees, and other security measures, are the responsibility of, and are conducted according to the rules prescribed by, the foreign government concerned.

§ 805.22 Releasing classified information.

(a) *Recording and routing material.* The chief of an office who plans to release classified information to bidders and contractors will first determine that the contractor or facility has been cleared, has been declared eligible, and can properly safeguard the information concerned (see paragraphs 2–108 and 2–109, AFR 205–4). In addition to §§ 805.6 through 805.10, which govern dissemination of classified material, all instructions for recording and preparing material for transmission will be observed. Classified material for contractors shall be addressed only to the official address of cleared facilities. When the information is intended for an individual (who has been authorized access), it shall be addressed to a cleared facility and marked for the attention of the individual concerned.

(b) *Defense Documentation Center (DDC).* DoD Instruction 5100.38 provides the authority and purpose of the Defense Documentation Center for Scientific and Technical Information (DDC). This instruction is implemented in the Air Force by AFR 80–29 (The Scientific and Technical Information (STINFO) Program). The primary function of the DDC is to acquire, store, announce, retrieve, and provide secondary distribution of scientific and technical documents, as well as other related functions. DDC service is available to educational, industrial, and scientific organizations which have been granted a facility security clearance of an appropriate degree according to AFR 205–4, provided the project office concerned approves the dissemination. The program does not apply to documents containing information of the following types: (1) Top Secret, (2) crypto material, (3) designated special categories of intelligence, (4) registered documents or publications, (5) contract proposals, administrative reports, orders, and memoranda, or (6) information furnished the U.S. by foreign governments when its dissemination is forbidden by the foreign government.

(i) Bidders, contractors, or grantees, and others participating in the AFSC Long-Range Planning Program, may be certified for unclassified DDC service by submitting a completed Field-of-Interest Register (FOIR) to DDC. For classified DDC service, they must submit the FOIR (DDC Form 20) to the ACO, who in turn will forward the form to the project office for approval. In addition, they must submit the Facility Clearance Register (DDC Form 62) to their cognizant security office for approval. DDC Forms 20 and 62 are available from Hq DDC (TIMA), Cameron Station, Alexandria, Va., 22314, or DDC Field Offices.

(ii) The project office is responsible for approving the FOIR, which establishes the proposed recipient's eligibility for DDC service and, where classified service is authorized, also constitutes certification of the proposed recipient's requirement for knowledge or classified information to perform a DoD contract, agreement, or grant (i.e., need-to-know). Information concerning the effective dates of contracts, agreements, or grants will be shown on the FOIR. Contracts, agreements, or grants so reported will not themselves be submitted to DDC. The project office is responsible for notifying DDC promptly of subsequent premature terminations of contracts, agreements, or grants, of extensions to them, and of any changes in need-to-know. Concurrent with these actions to approve and subsequently to terminate prematurely, the project office is responsible for notifying the appropriate cognizant security office of the establishment or disestablishment of a contractor's eligibility.

(iii) The cognizant security office of the proposed recipient is responsible for certifying the facility security clearance, which constitutes certification as provided in AFR 205–4 that the proposed recipient has a current clearance of the appropriate degree and has facilities to protect classified material of the specified classification category entrusted to him. The cognizant security office, in accordance with AFR 205–4, is responsible for notifying DDC should the revocation, suspension, termination, or inactivation of a clearance, or an unsatisfactory security condition, require the withholding or termination of classified DDC service.

§ 805.23 Sponsoring meetings.

(a) *Sponsorship by the Air Force.* When the subject matter to be discussed at meetings is of principal interest to the Air Force, the project commander primarily concerned shall be responsible for determining if the proposed meeting will serve an Air Force interest and, if so, he may approve and sponsor the meeting on behalf of the Department of Defense. When there is no apparent project commander, the major air command having primary functional responsibility in the Air Force for the subject matter may assume sponsorship on behalf of DoD.

NOTE: The approval and sponsorship of such contractor conducted meetings requires a positive finding that the meeting will serve a Government purpose and that it will provide a definite advantage to the United States. Such meetings normally will also serve to promote the functions and interests of the project office or staff agency charged with responsibility for the subject, project, or activity involved. Therefore, over-all responsibility for approval and sponsorship should normally be assumed by or assigned to the organizational entity having primary functional responsibility for the subject or project. However, when the interests of economy, efficiency, and security would be served best thereby, the sponsoring activity may request assistance from other military agencies or staff activities for the performance of some on-site functions.

(b) *Location of meetings.* Air Force agencies shall not approve the use of auditoriums, halls, gymnasiums, etc., located on the campus of a college or university for meetings when Top Secret or Secret information is to be disclosed in the meeting. Such buildings are not considered to be part of the cleared facility, since they are used primarily for campus activities such as plays,

athletic events, faculty meetings, student rallies, and other events open to the public. Moreover, they were not constructed or designed with any security considerations in mind and, consequently, are vulnerable to unauthorized visual, audio, or physical access. Meetings at which Top Secret or Secret information is to be disclosed may, however, be conducted at a U.S. Government installation or within a building, room, or laboratory located on the campus of a college or university provided that:

(1) The building, room, or laboratory has been identified by the cognizant security office as an integral part of the cleared facility, and

(2) The cognizant security office has, during the performance of the recurring inspections, determined that the security controls over the building, room, or laboratory are adequate and would preclude unauthorized access during the conduct of a classified meeting.

§ 805.24 Consultants.

(a) *Part-time Government employees.* Part-time Government employees include (1) Consultants who are employed by the Air Force without compensation (WOC), and (2) experts and consultants employed by the Air Force and compensated on a when-actually-employed (WAE) basis. After proper clearance and access authorization, these employees may be given access to classified material within the area of the Air Force agency concerned. They are not authorized to remove classified material from the Air Force agency, and it may not be sent to them.

(b) *Prime contractors.* Individuals who enter into a contract to provide personal services to an Air Force agency, which requires the consultant to have physical custody of classified information at his place of business, are considered prime contractors. These consultants must be granted a facility security clearance according to AFR 205–4 and the ISM, and their facility must be approved for storing classified information before they may take classified information outside the Air Force agency, or before it can be sent to them. These consultant facilities are subject to inspection by cognizant security offices.

(c) *Personal services consultants.* Personal services consultants are individuals who enter into a contract to provide personal services to an Air Force agency, wherein all service will be performed at the Air Force agency. These consultants may be granted a personnel security clearance according to AFR 205–4 and the ISM prior to being granted access to classified material. A facility clearance is not required, provided the certificate prescribed in paragraph 2–114.2b, AFR 205–4, is accomplished. They are not authorized to remove classified material from the Air Force agency, and it may not be sent to them.

(d) *Personal services contractors.* A personal services contractor is a contractor who enters into a contract for one or more of his employees to perform personal services for an Air Force agency. This service may be provided under two conditions:

(1) The contractor shall be cleared as a facility in accordance with AFR 205–4, if the performance of such services involves access to classified information and requires classified information to be in the physical custody of the contractor. The contractor and employees concerned must be granted personnel security clearances prior to being granted access to classified material. Also, the contractor's facility is subject to inspection by a cognizant security office.

(2) If the consultant services will be performed on the premises of the Air Force agency and the classified information not be removed from such premises, no facility clearance is required. The contractor and his employees performing the personal services must jointly execute the certificate prescribed in paragraph 2–114.2c, AFR 205–4. Those personnel requiring access to classified information must be granted a personnel security clearance prior to being granted access.

§ 805.25 Contractor's use of COMSEC material and crypto devices.

(a) General: Air Force classified cryptographic information and other communications security information is made available to DoD contractors, and to their subcontractors, vendors, and suppliers, under one or more of the following conditions:

(1) When the contractor requires the use of crytographic systems in the performance of his contract.

(2) When the contractor is required to accomplish research, development, or production of crytographic systems or equipment.

(3) When the contractor is required to install, maintain, or operate crytographic equipment for an activity of the U.S. Government.

§ 805.26 Personnel access authorizations for contractor employees.

(a) *Cognizant security command.* The commander of a major air command having security cognizance of a contractor's facility has the authority to effect interim and final personnel security clearances. This authority will be exercised regarding all Department of Defense clearances required at the facility, except those granted by the Army or the Navy according to AFR 205–4.

NOTE: Special authorization must be obtained in accordance with § 805.28 for the issuance of an interim Secret clearance for an immigrant alien, and for any interim Top Secret clearance.

(b) *Contracting command.* The commander of the major air command having responsibility for negotiating or administering a contract is responsible for effecting security clearances when:

(1) The Army or Navy command having security cognizance of the contractor's facility involved is unable to provide clearance service due to extenuating circumstances.

(2) Restricted Data classified Confidential is to be disclosed to U.S. citizen employees, and the facility involved is under Army or Navy security cognizance.

(c) *Clearance criteria.* Instructions for determining the eligibility of bidders and contractors and their employees to have access to classified defense information are contained in the Department of Defense Industrial Personnel Security Regulation.

§ 805.27 Denial, suspension, and revocation of clearances for contractor employees.

(a) *DoD policy.* Instructions which are published as an attachment to AFR 205–12 establish uniform standards and criteria applying to clearances for contractors and their employees. Paragraph 2–209, AFR 205–4, explains how to dispose of cases which involve the denial, suspension, or revocation of such clearances. Paragraph 2–202e, AFR 205–4, prescribes the action to be taken when a contractor employee terminates his employment before clearance action or review action has been completed.

(b) *Withdrawal of interim clearances.* The withdrawal of an interim personnel security clearance is not subject to the rules prescribed for the denial, suspension, or revocation of final clearances. In this connection, an interim facility security clearance must be withdrawn promptly if significant derogatory information (defined in AFR 205–12) is developed on an individual who was issued an interim personnel security clearance as part of the facility security clearance action. However, a final clearance for access to a lower category of classified information may not be revoked except as provided in paragraph 2–111d, AFR 205–4.

(c) *Derogatory information.* According to paragraphs 6 a, b, and d of the ISM, a contractor is required to give the cognizant security office information concerning: (1) Subversive activity, (2) compromises or suspected compromises of classified information, and (3) individuals whose access to classified information might not be clearly consistent with the interests of national security. In addition, Air Force commanders will submit to the cognizant security office and to contracting commanders certain information on technical representatives or similar type contractor personnel who have been or are being cleared for access to classified matter. Specifically, this will include information indicating that such access would not be consistent with the interests of the national security. An Air Force cognizant security commander who receives such information will take action as follows:

(1) For a person who has access or who is being cleared for access to classified information:

(i) If the information indicates that retention of a security clearance would constitute an immediate threat to the security interests of the United States, the procedures contained in AFISL letter to AFSC, AAC, ADC, SAC, and AFLC, subject: Emergency Suspension of Industrial Personnel Access Authorizations, April 8, 1963, will be followed.

(ii) If the facts indicate a need for further information, the OSI should be requested to initiate necessary investigation. When the reports of investigation are received and reviewed, an administrative determination will be made to do one of the following: (*a*) Process the case to the Director, Office of Industrial

Personnel Security Review; (b) issue a Letter of Consent; or (c) continue or administratively restore the clearance, as appropriate.

(2) For a person not referred to above, the derogatory information will be referred to the OSI. It will include a statement that the person does not have a clearance for, nor access to, classified information. The receipt of the information will be acknowledged to the contractor and the contractor will be advised to refer to the Government any future requirement for access to classified information.

§ 805.28 Interim Secret clearances; immigrant aliens.

The Secretary of the contracting military department may authorize the issuance of an interim Secret personnel security clearance for an immigrant alien. This authorization may be given only after a favorable National Agency Check.

§ 805.29 Foreign national employees of contractors.

This section applies to Air Force contracts awarded to U.S. firms in the United States which are to be performed either within or outside of the United States.

(a) *General.* Except as specified in paragraph 2–203, AFR 205–4, a foreign national is not eligible for a personnel security clearance. However, if the facts indicate an impelling necessity to permit disclosure of the classified information involved, the commander may request that a limited access authorization be approved.

(b) *Authority and criteria for approval.* A Deputy Chief of Staff (or an officer having an equivalent position) in Hq USAF who has primary interest in the procurement aspects of the contract (or contracts) involved may approve a request from a contractor for permission to use a foreign national on duties involving access to classified information, provided that:

(1) There is an impelling necessity in the interest of essential Air Force procurement operations to permit the foreign national to have such access. (A foreign national will never be used if a qualified individual who can be cleared is available for employment in the duties involved.)

(2) The person's employment is for a designated task or project and the classified information to be disclosed will be limited to Air Force information directly connected with a specific Air Force contract or contracts.

(3) Top Secret information, Restricted Data, or classified cryptographic systems or equipment will not be involved.

(4) The classified information is releaseable to the individual's government according to policy in AFR 200–9.

(5) As much of a Background Investigation as is feasible has been completed by the appropriate investigative agency.

(6) Concurrence is obtained from Hq USAF from the Assistant Chief of Staff, Intelligence, and the Inspector General.

(c) *Initial routing request.* (1) A request from a contractor for permission to use a foreign national employee on duties requiring access to classified information will be submitted to the contracting officer concerned. If there is more than one contract, the contractor should select the contracting officer who appears to have the greatest interest; however, each contract will be identified. Each request must include sufficient information to support the requirement of paragraphs (b)(1) and (2) of this section, and to permit an evaluation to be made. In addition, the request must specifically identify the classified information involved.

(2) If the immediate commander of the contracting officer believes the request to be sufficiently justified for further consideration in the Air Force, he will send it and his comments through command channels to the commander having direct responsibility for the project involved in the contract or contracts. If project responsibility rests in Hq USAF, the contracting command will route the request to the chief of the major staff office concerned.

(3) When the contracting and project offices are in different major air commands, correspondence regarding the use of a foreign national will follow the same channel used for other communications between the two offices.

(d) *Action by a project command.* (1) If it appears that the proposal for disclosing classified information meets the criteria for approval in paragraph (b) of this section, the request will be sent through project command channels to the chief of the office of primary responsibility in Hq USAF. Requests which are disapproved will be returned direct to the contracting officer.

(2) Recommendations for approval of a request must include complete information showing why approval is necessary. Also the basis for the classification assigned to the information involved must be stated.

(e) *Signatures on recommendations and approvals*—(1) *Recommendations.* The commander or deputy commander of each headquarters that recommends approval of a request must sign the recommendations. However, at a major air command headquarters the chief of staff or a general officer in the staff office having primary interest in the project may be authorized to sign for the commander.

(2) *Approvals.* In Hq USAF, an approval or concurrence must be signed by the officer designated in paragraph (b) of this section, or by his deputy or principal assistant, after the concurrences specified in paragraph (b)(6) of this section have been obtained.

(f) *Action after approval.* (1) The notification of approval of a request will be channeled through the project command to the contracting commander.

(2) The contracting officer will prepare and forward a letter of notification to the contractor. The instructions in this letter will be in the nature of a limited access authorization in the same form as prescribed in AFR 205–10 for foreign national employees of the Air Force. The "letter of limited access authorization" must show specifically and completely:

(i) The task or project and the contract or contracts on which duty assignment is authorized;

(ii) The highest classification and description of classified information to which the employee may be given access;

(iii) Restrictions against permitting access to designated types of classified information when circumstances indicate the need for such definitive instructions;

(iv) Applicable instructions concerning the security of classified documents; and

(v) Any other security requirement necessary to preclude unauthorized disclosure of classified information.

(3) The contracting officer will send copies of the "letter of limited access authorization" to:

(i) The project commander; and

(ii) The commander having security cognizance of the contractor's facility where the foreign national is employed (if industrial security cognizance has been assigned under AFR 205–4), or to the commander responsible for security supervision of the contractor's operations (see § 805.19).

By order of the Secretary of the Air Force.

FREDERICK A. RYKER,
Lt. Colonel, United States Air Force, Chief, Special Activities Group, Office of The Judge Advocate General.

[F.R. Doc. 64–6091; Filed, June 18, 1964; 8:49 a.m.]

Title 12—BANKS AND BANKING

Chapter II—Federal Reserve System

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg. H]

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

Establishment and Operation of Branches

§ 208.110 "Messenger service" provided by State member banks.

(a) The Board of Governors has been asked whether an arrangement under which a State member bank provides "messenger service" for a customer, subject to an agreement that the messenger acts as agent for the customer, would involve the operation of a branch by the bank.

(b) Section 9 of the Federal Reserve Act (12 U.S.C. 321) provides, in effect, that a State member bank, if permitted to do so by State law, may establish branches on the same terms and conditions and subject to the same limitations

and restrictions as are applicable to the establishment of branches by national banks, except that the approval of the Board of Governors, instead of the Comptroller of the Currency, shall be obtained before a branch may be established by a State member bank. It is apparent that it was the intent of Congress that national banks and State member banks should have substantially equal opportunity to establish branches.

(c) Section 5155 of the Revised Statutes (12 U.S.C. 36), relating to branches of national banks, provides that the term "branch" shall be held to "include any branch bank, branch office, branch agency, additional office, or any branch place of business * * * at which deposits are received, or checks paid, or money lent."

(d) Whether any of the banking transactions described in the law, or other banking transactions, are conducted at an "additional office" or other "place of business" can be determined only on the basis of particular factual situations. The question here presented refers only to "messenger service" provided by the Bank, without any indication of the purpose of the service or the exact circumstances in which it would be provided.

(e) It is assumed, however, that the service in question would involve picking up deposits at the respective addresses of particular customers and the payment of checks drawn by such customers on the bank; that the "messenger" normally would be an armored car owned by the bank or by an independent contractor; that the cost of the service would be borne by the bank; that, in the case of deposits, there would be a written agreement between the bank and the customer under which the messenger would act as agent of the customer and the bank would assume no liability for the funds collected until they were received by it from the messenger at the bank's premises; and that, in the case of payment of checks, the checks would be presented at the bank's premises by the messenger acting as agent of the customer and the proceeds received by the messenger for transmittal to the customer, with no liability on the part of the bank for such proceeds after their delivery to the messenger.

(f) Assuming the facts to be as stated above, the Board does not regard such arrangements as involving the establishment and operation of branches by State member banks. Whether the use of messenger service in other circumstances would constitute branch banking would, of course, have to be determined on the basis of the facts involved.

(12 U.S.C. 248(i). Interprets 12 U.S.C. 36 and 321)

Dated at Washington, D.C., this 9th day of June 1964.

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM,
[SEAL] MERRITT SHERMAN,
Secretary.

[F.R. Doc. 64-6072; Filed, June 18, 1964; 8:47 a.m.]

[Reg. H]

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

Undivided Profits as "Capital", "Capital Stock", or "Surplus"

§ 208.111 Whether undivided profits may be considered part of capital or surplus of member banks.

(a) The Board of Governors has been presented with the question whether a bank's undivided profits may be considered as part of its "capital stock", "capital", or "surplus" for the purposes of provisions of law imposing requirements or limitations upon member banks of the Federal Reserve System.

(b) It is obvious that undivided profits are not a part of a bank's "capital stock"; and Congress has explicitly indicated in the national banking laws that the more general term "capital" is limited to common stock and preferred stock (12 U.S.C. 51c).

(c) In the banking field, the undivided profits account traditionally represents a fluctuating amount as distinguished from the relatively fixed and permanent amount of a bank's "surplus" or "surplus fund". This distinction has been explicitly recognized by the Supreme Court of the United States:

> By incorporated banks the term [undivided profits] is commonly employed to designate the account in which profits are carried more or less temporarily, in contradistinction to the account called surplus in which are carried amounts treated as permanent capital, and which may have been derived from payments for stock in excess of par, or from profits which have been definitely devoted to use as capital. Edwards v. Douglas, 269 U.S. 204, 215 (1925)

(d) The Federal banking laws use the terms "undivided profits" and "surplus" as having different meanings. For example, with respect to the admission to membership in the Federal Reserve System of mutual savings banks having no capital stock, the Federal Reserve Act requires such a bank to have "surplus and undivided profits" not less than the amount of capital required for the organization of a national bank in the place in which the savings bank is located (12 U.S.C. 333). Similarly, various provisions of the National Bank Act distinguish between "undivided profits" and "surplus fund". Thus, a national bank may not declare dividends if its losses have exceeded its "undivided profits" (12 U.S.C. 56); and, until a national bank's "surplus fund" equals its common capital, it may not declare dividends unless a specified percentage of its net profits is carried to its "surplus fund" (12 U.S.C. 60).

(e) If undivided profits were regarded as a part of a bank's surplus or "surplus fund", such provisions for transfer of profits to surplus would be meaningless and the application of other provisions would be uncertain and impracticable. For example, subscriptions by member banks to Federal Reserve Bank stock are based upon the amount of the member bank's "capital stock and surplus" (12 U.S.C. 287), so that, if undivided profits were regarded as a part of "surplus", the amount of a bank's subscription to Reserve Bank stock would have to be increased and decreased continuously, an inconvenient and costly procedure that could not have been contemplated by Congress.

(f) It is recognized that the question whether undivided profits may be added to capital stock and surplus in calculating the lending limitations governing member banks is a matter for determination under applicable State law in the case of State banks and under the National Bank Act in the case of national banks, except as further limited by particular provisions of the Federal Reserve Act. For the reasons indicated above, it is the Board's opinion that undivided profits do not constitute "capital", "capital stock", or "surplus" for the purposes of provisions of the Federal Reserve Act, including those that limit member banks with respect to loans to affiliates (12 U.S.C. 371c), purchases of investment securities (12 U.S.C. 335), investments in bank premises (12 U.S.C. 371d), loans on stock or bond collateral (12 U.S.C. 248(m)), deposits with nonmember banks (12 U.S.C. 463), and bank acceptances (12 U.S.C. 372, 373), as well as provisions that limit the amount of paper of one borrower that may be discounted by a Federal Reserve Bank for any member bank or accepted as security for an advance to a member bank (12 U.S.C. 330, 345, 347).

(12 U.S.C. 248(i). Interprets 12 U.S.C. 24, 84, 248(m), 287, 330, 335, 345, 347, 371c, 371d, 372, 373, 463)

Dated at Washington, D.C., this 11th day of June 1964.

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM,
[SEAL] MERRITT SHERMAN,
Secretary.

[F.R. Doc. 64-6073; Filed, June 18, 1964; 8:47 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Agency

SUBCHAPTER E—AIRSPACE [NEW]

[Airspace Docket 64-SO-1]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Alteration of Federal Airways

On March 18, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 3476) stating that the Federal Aviation Agency proposed to realign segments of VOR Federal airways Nos. 11, 20, 70, and 837 in the vicinity of Greene County, Miss.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. The Air Transport Association of America (ATA) submitted the only comments.

The ATA recommended that the present alignment of the segment of VOR Federal airway No. 11 between Mobile, Ala.; and Laurel, Miss., be retained rather than aligning it via the Greene County VOR. They contend the proposed alignment would increase the en route mileage and would entail the tuning of an additional navigational facility. The realignment of V–11 via Greene County VOR would only increase the en route mileage by an additional two miles. The inclusion of the Greene County VOR in this airway structure would improve the navigational coverage on this airway segment and would more than offset the disadvantages cited by the ATA.

In addition, the ATA recommended that the segment of VOR Federal airway No. 20 north alternate from Mobile to Evergreen be realigned in part via the Mobile 034° True radial in lieu of the 015° True radial. The utilization of the 034° True radial would shorten the en route mileage for this airway segment and would still permit sufficient angular separation from the V–20 main airway segment at the Mobile VORTAC. Therefore, this recommended alignment of V–20 north alternate segment is being adopted herein.

The substance of the proposed amendments having been published and for the reasons stated herein and in the notice, § 71.123 (29 F.R. 1009, 1561, 3000) is amended as follows:

1. In V–11 "via Laurel, Miss.," is deleted and "via Greene County, Miss.; Laurel, Miss.;" is substituted therefor.

2. In V–20 "including an N alternate via INT of Mobile 015° and Evergreen 247° radials" is deleted and "including an N alternate via INT of Mobile 034° and Greene County, Miss., 068° radials" is substituted therefor.

3. In V–70 "Evergreen, Ala.;" is deleted and "Greene County, Miss.; Evergreen, Ala.;" is substituted therefor.

4. In V–837 "via Evergreen, Ala.;" is deleted and "via Greene County, Miss.; Evergreen, Ala.;" is substituted therefor.

These amendments shall become effective 0001 e.s.t., August 20, 1964.

(Sec. 307(a), 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 12, 1964.

D. E. BARROW,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64–6077; Filed, June 18, 1964; 8:47 a.m.]

[Airspace Docket 64–SW–17]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Modification of Control Zone and Control Area Extension

The purpose of these amendments to Part 71 [New] of the Federal Aviation Regulations is to alter the descriptions of the Pine Bluff, Arkansas, control zone and the Little Rock, Arkansas, control area extension. The Pine Bluff, Ark., radio beacon is scheduled to be decommissioned by June 25, 1964. Additionally, the description of the Pine Bluff control zone erroneously refers to a 5-mile radius zone in lieu of the correct radius of 3 miles. This action amends the description of the Pine Bluff control zone by revoking the extension based upon the 177° bearing from the radio beacon and corrects the improper reference to the 5-mile radius. It also amends the description of the Little Rock control area extension by replacing the radio beacon location with appropriate coordinates as the basis for describing an extension.

Since these amendments impose no additional burden on any person, notice and public procedure hereon are unnecessary and the amendments may be made effective without regard to the 30-day statutory period preceding effectiveness. Therefore, these amendments may become effective less than 30 days after publication.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective June 25, 1964, as hereinafter set forth.

In § 71.165 (29 F.R. 1073) the Little Rock control area extension is amended to read as follows:

Little Rock, Ark.

Within a 50-mile radius of the Little Rock RBN; that airspace SW of Little Rock extending from the 50-mile radius area bounded on the NW by V–54 and on the SE by V–16; that airspace S of Pine Bluff, Ark., within 10 miles E and 7 miles W of the 177° bearing from latitude 34°10'30" N., longitude 91°56'-15" W., extending from the 50-mile radius area to 20 miles S of latitude 34°10'30" N., longitude 91°56'15" W.; that airspace W of Hot Springs, Ark., within 7 miles NW and 10 miles SE of the Hot Springs VOR 076° and 256° radials, extending from the 50-mile radius area to 20 miles SW of the VOR, and that airspace N of Little Rock within 11 miles W and 7 miles E of the Little Rock AFB TACAN 341° radial, extending from the 50-mile radius area to 44 miles NW of the TACAN.

In § 71.171 (29 F.R. 1101) the Pine Bluff control zone is amended to read as follows:

Pine Bluff, Ark.

Within a 3-mile radius of Grider Field, Pine Bluff, Ark. (latitude 34°10'35" N., longitude 91°55'55" W.; and within 2 miles each side of the Pine Bluff VOR 186° and 006° radials extending from the 3-mile radius zone to 5 miles N of the VOR.

(Sec. 307(a) of the Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 11, 1964.

D. E. BARROW,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64–6076; Filed, June 18, 1964; 8:47 a.m.]

[Airspace Docket 63–CE–93]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Designation of Transition Area

On January 23, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 574) stating that the Federal Aviation Agency proposed to designate a transition area at Great Bend, Kans.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. Due consideration was given to all relevant matter presented.

The Air Transport Association commented that they found the proposal acceptable, provided that no increase in instrument approach weather minimums, loss of transition routes, or loss of straight-in approach capability from the facility to the airport will result from the action. It has been determined, however, that no straight-in approach minimums have existed in the past, and that weather minimums and transition routes will not be affected. No other comments were received.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective 0001 e.s.t., August 20, 1964, as hereinafter set forth.

Section 71.181 (29 F.R. 1160) is amended by adding the following transition area:

Great Bend, Kans.

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Great Bend Municipal Airport (latitude 38°20'50" N., longitude 98°52'00" W.), and within 2 miles each side of the 305° bearing from the Great Bend Municipal Airport, extending from the 7-mile radius area to 10 miles NW of the airport; and that airspace extending upward from 1,200 feet above the surface within 5 miles NE and 8 miles SW of the 305° bearing from Great Bend Municipal Airport, extending from the airport to 14 miles NW of the airport.

(Sec. 307(a) of the Federal Aviation Act of 1958; (49 U.S.C. 1348)

Issued in Washington, D.C., on June 11, 1964.

D. E. BARROW,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc 64–6079; Filed, June 18, 1964; 8:48 a.m.]

[Airspace Docket 63–SO–27]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Revocation of Reporting Point

On May 16, 1964, Federal Register Document No. 64–4910 was published in the FEDERAL REGISTER (29 F.R. 6437) and amended Part 71 [New] of the Federal Aviation Regulations in part by realigning VOR Federal airways Nos. 51, 140, 819, 830, and 887 via the new Highway, Tenn., VOR. These amendments are to become effective 0001 e.s.t., July 23, 1964.

The Highway Intersection (intersection of Nashville, Tenn., 064° and Crossville, Tenn., 343° True radials) is designated as a low altitude reporting point serving Victors 51, 140, 819, 830, and 887. With the realignment of these airways via the new Highway VOR, the Highway Intersection no longer serves a useful purpose and may be revoked. Such action is taken herein. In addition Federal Register Document 64–4910 Item 1,

b. V–51 referred to "Highway, Ky." This should have read "Highway, Tenn." Such change is made herein.

Since these amendments are minor in nature and impose no additional burden on any person, notice and public procedure hereon are unnecessary, and the effective date of the final rule as initially adopted may be retained.

In consideration of the foregoing, effective immediately, Federal Register Document 64–4910 (29 F.R. 6437) is altered as follows:

In Item 1., b., "Highway, Ky.;" is deleted and "Highway, Tenn.;" is substituted therefor.

Item 3., is added as follows:

3. In § 71.203 (29 F.R. 1211) the Highway INT reporting point is revoked.

(Sec. 307(a), 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 12, 1964.

D. E. BARROW,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64–6078; Filed, June 18, 1964; 8:48 a.m.]

Title 16—COMMERCIAL PRACTICES

Chapter I—Federal Trade Commission

[Docket 7887 o.]

PART 13—PROHIBITED TRADE PRACTICES

Grand Caillou Packing Co., Inc., et al.

Subpart—Discriminating in price under sec. 5, Federal Trade Commission Act: § 13.870 *Charges and prices;* § 13.893 *Lease versus sale.*[1]

[Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45; Cease and desist order, Grand Caillou Packing Company, Inc. (Houma, Louisiana) et al., Docket 7887, June 4, 1964]

In the Matter of Grand Caillou Packing Company, Inc., a Corporation, Emile M. Lapeyre, Individually, and as President and Director of Grand Caillou Packing Company, Inc., and Emile M. Lapeyre, Fernand S. Lapeyre, James M. Lapeyre, Andre C. Lapeyre, Felix H. Lapeyre, and Emile M. Lapeyre, Jr., Individually, as Co-Partners Trading and Doing Business as The Peelers Company, and as Representative of all of the Partners in The Peelers Company

Order requiring five members of a Louisiana family engaged in the development and distribution of shrimp processing machinery, of which they had a monopoly and which they leased to shrimp canners in the United States and sold to foreign canners, to cease discriminating in price between domestic lessees by such practices as charging shrimp canners in the North-Western United States approximately double the rate they charged the canners' competitors on the Gulf of Mexico; and to cease discriminating between foreign and domestic shrimp processors by selling their machinery abroad while refusing to sell to domestic canners, with result of maintaining static higher production costs at home and permitting lower costs which receded with increased production to foreigners, thus creating the likelihood that foreigners would enlarge their penetration of the United States market and making it increasingly difficult for domestic producers to compete for foreign markets.

The order to cease and desist, including further order requiring report of compliance therewith, is as follows:

It is ordered, That the respondents, Emile M. Lapeyre, Fernand S. Lapeyre, James M. Lapeyre, Felix H. Lapeyre, and Emile M. Lapeyre, Jr., individually, as copartners trading and doing business as The Peelers Company, and as representatives of all of the partners in The Peelers Company, and their agents, representatives, and employees, directly or indirectly, through any existing or succeeding corporation, partnership, sole proprietorship, or other device, in connection with the distribution in commerce, as "commerce" is defined in the Federal Trade Commission Act, of any shrimp peeling, cleaning and separating machinery or improvements thereto now or hereafter controlled by respondents, do forthwith cease and desist from:

(1) Discriminating between lessees of such machinery by charging higher rental or use rates to any lessee than are charged to any other lessee.

For the purposes of this proceeding, lease or rental terms which result in any lessee paying a higher rate than the rate charged any other lessee for use of respondents' machines for the same period of time or through the same number of mechanical revolutions or operations shall be deemed discriminatory.

(2) Discriminating between foreign and domestic shrimp processors by refusing to sell such machinery to domestic processors upon the same terms and conditions afforded to foreign processors.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with the order to cease and desist contained herein.

Issued: June 4, 1964.

By the Commission.

[SEAL] JOSEPH W. SHEA,
Secretary.

[F.R. Doc. 64–6080; Filed, June 18, 1964; 8:48 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Animal Feed or Animal Feed Supplements

Subpart D—Food Additives Permitted in Food for Human Consumption

THIABENDAZOLE

1. The Commissioner of Food and Drugs, having evaluated the data submitted in a petition (FAP 1372) filed by Merck Chemical Division, Merck and Company, Rahway, New Jersey, and other relevant data, has concluded that the food additive regulations should be amended to provide conditions under which thiabendazole may be safely used orally as an anthelmintic for cattle. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 as amended; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471) the food additive regulations are amended by adding to Subpart C the following new section:

§ 121.260 Thiabendazole.

Thiabendazole may be safely used in the treatment of food-producing animals in accordance with the following conditions:

(a) The additive is the chemical 2-[4'-thiazolyl]-benzimidazole, $C_{10}H_7N_3S$, conforming to the following specifications:

(1) Ultraviolet assay (A 1 percent 0.1n HCl, 1 cm., 302 mμ= 95–103 percent.

(2) Ultraviolet identity ratio (A_{243}/A_{302})=0.485–0.520.

(3) Melting range 296° to 303° C.

(4) Heavy metals (as lead) maximum 0.005 percent.

(b) Permitted uses of thiabendazole are described in tabular form in this section.

(c) The additive is used or intended for use as follows:

[1] New.

TABLE 1—MISCELLANEOUS

Principal ingredient	Dose	Combined with—	Dose	Limitations	Indications for use
1. Thiabendazole	3 gm. per 100 lb. body weight.			For cattle; as a single oral dose; may repeat once in 2 to 3 weeks; not for dairy animals in production; do not treat within 30 days of slaughter.	Treating infestations of gastrointestinal roundworms (genera *Trichostrongylus spp., Ostertagia spp.*).
2. Thiabendazole	5 gm. per 100 lb. body weight.			do	Treating severe infestations of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Ostertagia spp.*); treatment of infestations of *Cooperia* species.

(d) To assure safe use, the label and labeling of the additive, any combination of additives, and final dosage form, and any feed additive premix, feed additive concentrate, feed additive supplement, or complete feed prepared therefrom, shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive or additives.

(2) A statement of the quantity or quantities of each contained therein.

(3) Adequate directions and warnings for use.

2. Based upon an evaluation of the data before him, and proceeding under the authority of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(4), 72 Stat. 1786 as amended; 21 U.S.C. 348(c)(4)), the Commissioner of Food and Drugs has concluded that where cattle have been treated with thiabendazole in accordance with § 121.260 tolerance limitations are required in order to assure that the edible products of cattle are safe for consumption. Therefore, Subpart D is amended by adding thereto the following new section:

§ 121.1153 Thiabendazole.

A tolerance of zero is established for residues of thiabendazole in milk and in the uncooked edible tissues and by-products of cattle.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c) (1), (4), 72 Stat. 1786 as amended; 21 U.S.C. 348 (1), (4))

Dated: June 15, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 64-6064; Filed, June 18, 1964; 8:46 a.m.]

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Animal Viruses, Serums, Toxins, Antitoxins, and Analogous Products

For the purpose of clarifying the status of the above-identified animal drugs under the provisions of the Federal Food, Drug, and Cosmetic Act and effecting consistency with existing regulations, § 130.2 of the new-drug regulations (21 CFR 130.2; 28 F.R. 6377) is amended as indicated below, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052 as amended, 52 Stat. 1055; 21 U.S.C. 355, 371(a)) and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471).

Section 130.2 is amended by redesignating the present text of the section as paragraph (a) and by adding to the section a new paragraph designated as (b). As amended § 130.2 reads as follows:

§ 130.2 Biologics; products subject to license control.

(a) A new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

(b) A new drug produced and distributed in accordance with §§ 103.1 to 103.3 of Title 9 of the Code of Federal Regulations, issued under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.) shall not be deemed to be subject to section 505 of the Federal Food, Drug, and Cosmetic Act.

Notice and public procedure and delayed effective date are not necessary prerequisites to the promulgation of this order, since the amendment is interpretative and serves to clarify existing regulations.

Effective date. This order will become effective upon publication in the FEDERAL REGISTER.

(Secs. 505, 701(a), 52 Stat. 1052 as amended, 52 Stat. 1055; 21 U.S.C. 355, 371(a))

Dated: June 15, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 64-6065; Filed, June 18, 1964; 8:46 a.m.]

Title 24—HOUSING AND HOUSING CREDIT

Chapter II—Federal Housing Administration, Housing and Home Finance Agency

SUBCHAPTER B—PROPERTY IMPROVEMENT LOANS

PART 201—CLASS 1 AND CLASS 2 PROPERTY IMPROVEMENT LOANS

Miscellaneous Amendments

1. In § 201.1 paragraph (i)(4) is amended to read as follows:

§ 201.1 Definitions.

* * * * *

(i) * * *

(4) A mutually binding contract for the purchase of the property where the borrower is rightfully in possession and the purchase price is payable in installments.

* * * * *

2. In § 201.9 paragraphs (a) and (b)(1) are amended to read as follows:

§ 201.9 Refinancing.

(a) *General requirements.* New obligations to liquidate loans previously reported for insurance pursuant to title I of the Act, whether or not an additional amount has been advanced, will be covered by insurance if the new obligations meet the requirements of all applicable regulations in this part and the special provisions of this section.

(b) *Maximum maturity.* (1) A Class 1(a) loan or a Class 2(a) loan may be refinanced for an additional period not in excess of 5 years and 32 days from the date of the refinancing, provided that the term of the new note does not extend beyond 10 years from the date of the original note.

* * * * *

(i) * * *

3. In § 201.11 paragraphs (b), (c), and (e)(2) are amended to read as follows:

§ 201.11 Claims.

* * * * *

(b) *Claim after default.* Claim may be filed after default, provided demand has been made upon the debtor for the full unpaid balance of the note. For the purpose of determining the date of default, any payments received on an account, including payment on judgments predicated thereon, shall be applied to the earliest unpaid installment.

(c) *Maximum claim period.* (1) Claim shall be filed no later than 31 days after the due date of the final installment provided for in the note. In computing a claim, interest will not be allowed for any period in excess of 9 months and 31 days from the date of default as provided in paragraph (e) of this section.

(2) If at the time of default or at any time subsequent to the default a person primarily or secondarily liable for the repayment of a loan is a "person in military service" as such term is defined in the Soldier's and Sailor's Civil Relief Act of 1940, as amended, the period during which he is in military service shall be excluded in computing the time within which claim is to be filed for reimbursement under the provisions of this section.

* * * * *

(e) *Claim amount.* * * *

(2) (i) 90 percent of the uncollected earned interest to the date of default, plus 90 percent of the interest at 5 percent per annum on the outstanding principal balance computed for the lesser of either of the following periods of time:

(*a*) The date of default to the date of application for reimbursement of loss, or

(*b*) A date 9 months and 31 days from the date of default.

(ii) In no event shall the total interest computed under subdivision (i) of this paragraph exceed the maximum permissible financing charge on the principal amount outstanding 9 months and 31 days from the date of default.

* * * * *

(Sec. 2, 48 Stat. 1246, as amended; 12 U.S.C. 1703)

Issued at Washington, D.C., June 15, 1964.

PHILIP N. BROWNSTEIN,
Federal Housing Commissioner.

[F.R. Doc. 64-6074; Filed, June 18, 1964; 8:47 a.m.]

Title 29—LABOR

Subtitle A—Office of the Secretary of Labor

PART 20—OCCUPATIONAL TRAINING OF UNEMPLOYED PERSONS

Change in Reduced Training Allowance

Pursuant to authority contained in section 207 of the Manpower Development and Training Act of 1962 (42 U.S.C. 2587), I hereby amend 29 CFR 20.35(e) in the light of the amendments to the Act made by section 3(a)(5) of Public Law 88-214, as set forth below.

The provisions of section 4 of the Administrative Procedure Act (5 U.S.C. 1003) which require notice of proposed rule making, opportunity for public participation, and delay in effective date, are not applicable because this rule involves only matters relating to public benefits. I do not believe such procedures will serve a useful purpose here. Accordingly, this amendment shall be effective on and after April 13, 1964.

As amended, paragraph (e) of 29 CFR 20.35 reads as follows:

§ 20.35 Amount of training allowances.

The amount of the training allowance shall be as follows:

* * * * *

(e) *Reduced training allowance.* The training allowance (regular, increased, youth, or supplemental) of an on-the-job trainee shall be reduced by two and one-half percent of such allowance for each compensated hour of the week. The training allowance (regular, increased, youth, or supplemental) of a person engaged in full-time training at a training or educational institution authorized under section 231 of the Act shall not be reduced with respect to his earnings during the first 20 hours worked, but shall be reduced in an amount equal to his full earnings for hours worked in excess of 20 hours per week. Except as the Secretary shall provide otherwise, earnings as used in this section shall mean remuneration, the receipt of which is applied to reduce the amount of unemployment compensation due under the applicable State unemployment insurance law. For this purpose dollar amounts forgiven under the State law shall be included as earnings, but earnings shall not include remuneration for work on the family farm by a member of a farm family with an annual net farm family income of less than $1,200. No allowance to which an individual may otherwise be entitled under this Act shall be diminished in any respect because of his receipt or entitlement to any supplemental unemployment benefits or separation allowances provided under any collective bargaining agreement.

* * * * *

(Sec. 207, 76 Stat. 29)

Signed at Washington, D.C., this 12th day of June 1964.

W. WILLARD WIRTZ,
Secretary of Labor.

[F.R. Doc. 64-6058; Filed, June 18, 1964; 8:45 a.m.]

Title 47—TELECOMMUNICATION

Chapter I—Federal Communications Commission

[FCC 64-523]

PART 1—PRACTICE AND PROCEDURE

PART 21—DOMESTIC PUBLIC RADIO SERVICES (OTHER THAN MARITIME MOBILE)

Miscellaneous Amendments

At a session of the Federal Communications Commission held at its offices in Washington, D.C., on the 10th day of June 1964;

The Commission having under consideration Public Laws 88-306 and 88-307 approved by the President on May 14, 1964; and

It appearing, that P.L. 88-306 amends section 309(e) of the Communications Act to provide for the filing of petitions for intervention within 30 days after publication in the FEDERAL REGISTER of the hearing issues or any substantial amendment thereto; and

It further appearing, that P.L. 88-307 amends section 309(c)(2)(G) of the Communications Act to authorize the issuance of a 60 day special temporary authorization (STA) for non-broadcast operation pending the filing of an application for regular operation; and

It further appearing, that the rules and regulations of the Commission should be amended to implement the aforementioned public laws; and

It further appearing, that authority for the changes set forth below is contained in sections 4 (i) and (j), 303(r), and 309 (c)(2)(G) and (e) of the Communications Act of 1934, as amended; and

It further appearing, that the changes set forth in the attached Appendix are procedural in nature, and hence that the prior notice and effective date provisions of section 4 of the Administrative Procedure Act do not apply; and

It further appearing, that the rules adopted herein pertaining to the issuance of 60 day STA's should apply to any application for an STA filed on or after the effective date of this order; and

It further appearing, that the rules adopted herein pertaining to the filing date of petitions for intervention should apply to all such petitions filed on or after the effective date of this order: *Provided, however,* That in cases where the hearing issues or any substantial amendment thereto were published in the FEDERAL REGISTER prior to the effective date of this order, any person may file a petition for intervention within 30 days after the effective date of this order or not later than 10 days prior to the date of hearing, whichever is earlier:

It is ordered, Effective June 18, 1964, that Parts 1 and 21 of the rules and regulations are amended as set forth below.

(Secs. 4, 303, 309, 48 Stat. 1066, 1082, 1085, as amended; 47 U.S.C. 154, 303, 309)

Released: June 15, 1964.

FEDERAL COMMUNICATIONS COMMISSION,[1]
[SEAL] BEN F. WAPLE,
Secretary.

1. Section 1.223 (a), (b), and (d) is amended to read as follows:

§ 1.223 Petitions to intervene.

(a) Where, in cases involving applications for construction permits and station licenses, or modifications or renewals thereof, the Commission has failed to notify and name as a party to the hearing any person who qualifies as a party in interest, such person may acquire the status of a party by filing, under oath and not more than 30 days after the publication in the FEDERAL REGISTER of the hearing issues or any substantial

[1] Commissioners Henry, Chairman; and Bartley absent.

amendment thereto, a petition for intervention showing the basis of its interest. Where such person's interest is based upon a claim that a grant of the application would cause objectionable interference under applicable provisions of this chapter to such person as a licensee or permittee of an existing or authorized station, the petition to intervene must be accompanied by an affidavit of a qualified radio engineer which shall show, either by following the procedures prescribed in this chapter for determining interference in the absence of measurements or by actual measurements made in accordance with the methods prescribed in this chapter, the extent of such interference. Where the person's status as a party in interest is established, the petition to intervene will be granted.

(b) Any other person desiring to participate as a party in any hearing may file a petition for leave to intervene not later than 30 days after the publication in the FEDERAL REGISTER of the hearing issues or any substantial amendment thereto. The petition must set forth the interest of petitioner in the proceedings, must show how such petitioner's participation will assist the Commission in the determination of the issues in question, and must be accompanied by the affidavit of a person with knowledge as to the facts set forth in the petition. The presiding officer, in his discretion, may grant or deny such petition or may permit intervention by such persons limited to particular issues or to a particular stage of the proceeding.

* * * * *

(d) Any person desiring to file a petition for leave to intervene later than 30 days after the publication in the FEDERAL REGISTER of the hearing issues or any substantial amendment thereto shall set forth the interest of petitioner in the proceedings, show how such petitioner's participation will assist the Commission in the determination of the issues in question, and set forth reasons why it was not possible to file a petition within the time prescribed by paragraphs (a) and (b) of this section. Such petition shall be accompanied by the affidavit of a person with knowledge of the facts set forth in the petition, and where petitioner claims that a grant of the application would cause objectionable interference under applicable provisions of this chapter, the petition for leave to intervene must be accompanied by the affidavit of a qualified radio engineer showing the extent of such alleged interference according to the methods prescribed in paragraph (a) of this section. If, in the opinion of the presiding officer, good cause is shown for the delay in filing, he may in his discretion grant such petition or may permit intervention limited to particular issues or to a particular stage of the proceeding.

2. Section 1.962(b)(5) is amended to read as follows:

§ 1.962 Public notice of acceptance for filing; petitions to deny applications of specified categories.

* * * * *

(b) * * *

(5) A special temporary authorization not to exceed 30 days where the applicant does not contemplate the filing of an application for regular operation, or not to exceed 60 days pending or after the filing of an application for regular operation.

* * * * *

3. Section 21.27 (a)(6) and (f) is amended to read as follows:

§ 21.27 Processing of applications.

(a) * * *

(6) A special temporary authorization not to exceed 30 days where the applicant does not contemplate the filing of an application for regular operation, or not to exceed 60 days pending the filing of an application for regular operation; or

* * * * *

(f) If, in the case of any application to which § 21.26(a) applies, a substantial and material question of fact is presented, or the Commission, for any reason, is unable to make the finding specified in that section, it shall formally designate the application for hearing on the grounds or reasons then obtaining and shall forthwith notify the applicant and all other known parties in interest of such action and the grounds and reasons therefor, specifying with particularity the matters and things in issue, but not including issues or requirements phrased generally. When the Commission has so designated an application for hearing, any party in interest who is not notified by the Commission of such action, may acquire the status of a party to the proceeding thereon by filing a petition for intervention, showing the basis of his interest, at any time not more than 30 days after the publication in the FEDERAL REGISTER of the hearing issues or any substantial amendment thereto. Any hearing subsequently held upon such application shall be a full hearing in which the applicant and all other parties in interest shall be permitted to participate. The burden of proceeding with the introduction of evidence and the burden of proof shall be upon the applicant, except that, with respect to any issue presented by a petition to deny or a petition to enlarge the issues, such burdens shall be as determined by the Commission.

* * * * *

[F.R. Doc. 64-6101; Filed, June 18, 1964; 8:50 a.m.]

Proposed Rule Making

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

INCOME TAX; RENTS OR ROYALTIES DERIVED IN THE ACTIVE CONDUCT OF A TRADE OR BUSINESS

Notice of Hearing

The proposed amendment to the regulations under section 954 of the Code, relating to rents or royalties derived in the active conduct of a trade or business, was published in the FEDERAL REGISTER for May 15, 1964.

A public hearing on the provisions of this proposed amendment to the regulations will be held on Tuesday, June 30, 1964, at 10:00 a.m., e.d.t., in Room 3313, Internal Revenue Building, Twelfth and Constitution Avenue NW., Washington, D.C.

Persons who plan to attend the hearing are requested to notify the Commissioner of Internal Revenue, Attention: CC:LR, Washington, D.C., 20224, by June 26, 1964.

[SEAL] CHARLES R. SIMPSON,
Director, Legislation and Regulations Division, Internal Revenue Service.

[F.R. Doc. 64-6121; Filed, June 18, 1963; 8:52 a.m.]

DEPARTMENT OF LABOR

Wage and Hour Division

[29 CFR Part 545]

FABRIC AND LEATHER GLOVES; PUERTO RICO

Proposed Piece Rates

Pursuant to section 6(a)(2) of the Fair Labor Standards Act of 1938 (29 U.S.C. 206(a)(2)), Reorganization Plan No. 6 of 1950 (3 CFR 1949-53 Comp., p. 1004), and General Order No. 45-A of the Secretary of Labor (15 F.R. 3290), I hereby propose to revise Schedule C of 29 CFR 545.13 by increasing the piece rates appearing thereon commensurate with increases in the minimum hourly wage rates now applicable under the wage order issued in accordance with the recommendations of review committee No. 7 for the fabric and leather glove industry in Puerto Rico (29 F.R. 7149).

Any person interested in this proposal may file a written statement of data, views, or argument regarding it with the Administrator of the Wage and Hour and Public Contracts Divisions, United States Department of Labor Building, 14th Street and Constitution Avenue NW., Washington, D.C., 20210, within 15 days after this notice is published in the FEDERAL REGISTER.

The proposed revised schedule read as follows:

§ 545.13 Piece rates established in accordance with § 545.9.

* * * * *

SCHEDULE C—PRICE RATE SCHEDULE FOR THE FABRIC AND LEATHER GLOVE INDUSTRY IN PUERTO RICO [1]

No.	Operation	Ladies' woven or knitted fabric gloves (1)	Leather gloves [2]		Unit of payment
			Ladies' (2)	Men's (3)	
		Cents	*Cents*	*Cents*	
188	Buttons, slip stitches with tape, 1 button per glove.	----------	----------	75.000	Per dozen pairs.
189	Buttonholes, stitched in and outside, 1 buttonhole per glove.	----------	----------	100.000	Do.
190	Crede stitch, 5 to 6 stitches per inch	0.391	----------	----------	Per inch.
191	Egyptian stitch, 5 to 6 stitches per inch	----------	0.686	----------	Do.
192	Feather stitch, 5 to 6 stitches per inch	.469	.862	----------	Do.
193	Large stitch (husky), 5 to 6 stitches per inch	----------	----------	.617	Do.
194	Regular stitch, 5 to 6 stitches per inch	.308	.647	.617	Do.
195	Slip stitch, hem only, 5 to 6 stitches per inch	.199	.442	.442	Do.
196	Slip stitch, reinforcement on slit, 5 to 6 stitches per inch, when sewing has been faced on by machine.	----------	.442	.442	Do.
197	Swagger stitch, 5 to 6 stitches per inch	.308	.647	.617	Do.
198	Whip stitch, 5 to 6 stitches per inch	.308	.647	.617	Do.

[1] Piece rates apply only to hand-sewing operations. For description of operations included under "hand-sewing" see definitions in applicable section of the wage order.

[2] The hourly minimum wage rates applicable to leather gloves are also applicable to combination leather and fabric gloves. However, piece rates for combination leather and fabric gloves must be set by employers in accordance with section 545.10.

(52 Stat. 1062, as amended; 29 U.S.C. 206)

Signed at Washington, D.C., this 15th day of June 1964.

CLARENCE T. LUNDQUIST,
Administrator.

[F.R. Doc. 64-6098; Filed, June 18, 1964; 8:49 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 121, 130]

EDIBLE PRODUCTS OF ANIMALS TREATED WITH EXPERIMENTAL DRUGS OR FOOD ADDITIVES

Proposed Authorization for Marketing

Under the authority provided in the Federal Food, Drug, and Cosmetic Act (secs. 409, 505, 701, 52 Stat. 1052 as amended; 52 Stat. 1055 as amended; 72 Stat. 1785; 21 U.S.C. 348, 355, 371), and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), notice is given of the intention of the Commissioner to amend certain portions of the food additive and new-drug regulations for the purpose of permitting the marketing of edible products of food-producing animals that have been treated with an experimental drug and/or food additives, under authorization obtained from the Food and Drug Administration and under certain specified conditions. The amendments proposed are as follows:

1. It is proposed to amend § 121.75 *Exemption for investigational use* by designating the present text of the section as paragraph (a) and by adding to the section the following new paragraphs, designated as (b) and (c):

§ 121.75 Exemption for investigational use.

* * * * *

(b) The Commissioner may issue an authorization to provide for the marketing of edible products of food-producing animals that have been treated with an experimental drug and/or food additive, under the following conditions:

(1) The authorization is limited to the marketing of edible products from a specific group or groups of animals identified in the application for authorization.

(2) Data have been presented to establish that the edible products of the test animals shall be free of residues of the additive or its metabolites under the specified conditions of the experimental study.

(3) A designated responsible person is in charge of the experiment to insure that the animals have been handled in accordance with the conditions specified in the application, so as to eliminate any residues from the edible products.

(c) A request for an authorization shall be submitted in triplicate, addressed to the Commissioner of Food and Drugs, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C., 20204. This request shall include the following:

(1) The name and all available pertinent information concerning the drug and/or food additive, including its chemical identity and composition and its physical, chemical, and biological properties, including specifications prescribing the minimum content of the desired

component(s), and identifying and limiting the reaction byproducts and other impurities to the extent known. Such information may be incorporated by reference if it is already in a new-drug application, food additive petition master file, or other record on file with the Food and Drug Administration. Authorization to refer to any confidential matter on file should be made a part of the request.

(2) A description of the analytical method used to determine the residues, including data to establish the sensitivity and validity of the method. Where adequate information on the dissipation of residues has been obtained by radioactive tracer studies a confirming chemical or biological method may not be necessary.

(3) Complete information on the methods, duration, and level of administration of the additive, and the purpose and scope of the proposed experimental studies, including the location and approximate number of animals to be treated and names and addresses of the responsible investigators involved.

(4) Locations of the proposed place or places of slaughter if the animals are to be slaughtered for food. If this information is not available, an explanation of why it is not available should be included.

(5) All residue analyses of the additive and its metabolite that have been made on the edible products of the animals treated with drugs and/or food additive in the same or similar manner as that in the proposed experimental studies, information on the method of taking the samples, and the analytical methods used in determining the residues and the withdrawal times or other practices followed to insure absence of residues in the animal products to be offered for food purposes.

(6) The kind and number of residue analyses to be made on the edible products obtained from the animals used in the proposed experimental studies; and if none are to be made, a statement of why such analyses are not deemed necessary or feasible.

§ 130.3 [Amended]

2. It is proposed to amend § 130.3 *New drugs for investigational use; exemptions from section 505(a)* by deleting from paragraph (f)(1) the last sentence, and substituting therefor the following new sentence: "None of the edible products from animals used in such tests shall be used for food purposes unless the sponsor or investigator holds a valid authorization issued in accordance with § 121.75(b) providing for such use."

All interested persons are invited to present their views in writing regarding the proposals published in this notice. Such views and comments should be submitted, preferably in quintuplicate, to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, within 30 days from the date of publication of this notice in the FEDERAL REGISTER.

Dated: June 15, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 64-6067; Filed, June 18, 1964; 8:47 a.m.]

[21 CFR Part 130]

VETERINARY NEW DRUGS FOR INVESTIGATIONAL USE

Proposed Exemptions

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701, 52 Stat. 1052, 1055; 21 U.S.C. 355, 371) and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), proposes to amend the new-drug regulations (21 CFR Part 130) as hereinafter set forth, and hereby offers an opportunity to all interested persons to submit their views in writing with reference to this proposal to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, within 60 days from the date of publication of this notice in the FEDERAL REGISTER. Views and comments should be submitted in triplicate.

1. It is proposed to change the section heading of § 130.3 to read:

§ 130.3 New drugs for human use; exemptions for investigational use from section 505(a).

2. It is proposed to add to Part 130 the following new section:

§ 130.3a New drugs for veterinary use; exemptions for investigational use from section 505(a).

A shipment or other delivery of a new drug intended for laboratory testing or clinical investigational use in animals shall be exempt from section 505(a) of the act if all the following conditions are met:

(a) Drugs for laboratory testing only. (1) Neither the animals nor products derived therefrom (meat, milk, eggs, etc.) are used for food purposes.

(2) The label bears the statement "Caution: New drug—Limited by Federal (or United States) law to laboratory testing. Not for use in humans. Not for use in or on animals, the products of which (meat, milk, eggs, etc.) are to be used for food."

(3) The person or firm shipping a new drug for laboratory testing maintains records of such shipments for 2 years after shipment and delivery of the drug. These records shall be available to any authorized employee of the Food and Drug Administration for inspection at all reasonable times.

(4) The person or firm shipping a new drug for investigational use under this section uses due diligence to insure that the drug will actually be used for testing purposes.

(b) Drugs for clinical investigation. (1) Prior to the shipment of the drug, a signed statement containing the following information must be submitted to the Food and Drug Administration by a sponsor seeking an exemption under this section:

(i) A complete statement of the qualitative and quantitative composition of the product, including the best available descriptive names of any new or novel compounds; a summary of the available scientific knowledge of the drug, including references to the scientific literature; a summary of any prior investigation of the drug, the conditions for which it is under investigation, and a general outline of the investigation to be undertaken; the recommended dosage and route of administration; and all the required warning statements to prevent possible misuse. (Upon request, the detailed protocols of any prior investigations of the drug, literature or other information deemed necessary by the Food and Drug Administration to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations of the drug shall be submitted.)

(ii) Copies of all labeling and other information to be supplied to the investigators. (The labeling and other information furnished each investigator shall be adequate to inform him of all relevant hazards, contraindications, side effects, and precautions suggested by prior investigations and experience with the drug. No representations shall be made that the safety or usefulness of the drug for the purposes to be investigated has been established unless the safety of the drug has been established by prior investigations and the purpose of the current investigations is solely to determine the usefulness of the drug.)

(iii) A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clincial investigations made with the drug. (Such information may be incorporated by reference, if it is already in a new-drug application, food additive petition, master file, or other record on file with the Food and Drug Administration. Authorization to refer to any confidential matter should be made a part of the submission.)

(iv) The name, address, and qualification of each investigator and the individual, if not the investigator, who will monitor the investigation. (Additional investigators may be added provided the above information concerning the additional investigators is promptly submitted to the Food and Drug Administration.)

(v) The location, the species, and approximate number of animals to be used

in the investigation and the estimated duration of the investigation. (When the drug is intended for investigational use in the treatment of sporadic diseases, the amounts of the drug to be sent each investigator may be substituted for the number of animals in the investigation.)

(vi) A statement that the sponsor has obtained a signed statement for each investigator containing the following:

(a) A brief summary of the investigator's qualifications.

(b) The investigator's commitment that he will:

(1) Furnish his reports to the sponsor of the investigation;

(2) Report promptly to the sponsor any adverse effect that may reasonably be regarded as caused by the new drug, and if the adverse effect is alarming, it shall be reported immediately;

(3) Make an adequate report of the investigation to the sponsor promptly after its completion, including the disposition of any test animals authorized for food use;

(4) Use the drug only in the authorized manner if authorization is obtained to use edible products derived from the test animals for food purposes; and

(5) Maintain adequate records of the disposition of all receipts of the drug, including dates, quantities, and use in animals and, if the investigation is terminated, return to the sponsor or at his direction destory any unused supply of the drug.

(vii) A statement that the sponsor will notify the Food and Drug Administration if the investigation is discontinued, and the reason therefor.

(viii) A statement that the sponsor will notify each investigator if a new-drug application is approved, or if the investigation is discontinued.

(ix) If the drug is to be sold, a full explanation why sale is required and should not be regarded as the commercialization of a new drug for which an application is not approved.

(2) The label bears the following statement and information:

(i) "Caution: New drug—Limited by Federal (or United States) law to investigational use in animals. Not for use in humans. Food use of animal products derived from test animals prohibited without authorization under the Federal Food, Drug, and Cosmetic Act."

(ii) Any warning or withdrawal statement necessary to prevent possible misuse.

(3) Records of all shipments, including the name and address of the investigator to whom the drug was sent, and date, quantity, and batch or code number, are maintained by the shipper until 2 years after a new-drug application is approved for the drug, or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration is so notified. These records are available to any authorized employee of the Food and Drug Administration for inspection at all reasonable times.

(4) Investigators shall maintain records of the disposition of all investigational drugs used for clinical investigation in animals until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. These records shall be available to any authorized employee of the Food and Drug Administration for inspection at all reasonable times.

(5) The sponsor promptly investigates and reports to the Food and Drug Administration and to all investigators any findings associated with use of the drug that may suggest significant hazards, contraindications, side effects, and precautions pertinent to the safety of the drug. If the finding is alarming, it is reported immediately and the clinical investigation discontinued until the finding is adequately evaluated and a decision reached that it is safe to proceed.

(6) If the investigations adduce facts showing that there is substantial doubt that they may be continued safely in relation to the drug's potential therapeutic effects, the sponsor shall promptly discontinue the investigation, notify all investigators and the Food and Drug Administration, recall or destroy all stocks of the drug outstanding, and furnish the Food and Drug Administration with a full report of the reason for discontinuing the investigation. The Food and Drug Administration will be prepared to confer with the sponsor on the need to discontinue the investigation.

(7) The sponsor shall discontinue shipments or deliveries of the new drug to any investigator who has repeatedly or deliberately failed to maintain or make available his records or reports of his investigations.

(8) Whenever a sponsor submits to the Commissioner the name of an investigator known to the Commissioner as having repeatedly or deliberately failed to comply with the conditions of these exempting regulations, the Commissioner will notify the sponsor that the investigator is not entitled to receive investigational-use drugs, and such investigator shall not be supplied any investigational-use drug until adequate assurance is provided to and accepted by the Commissioner that the conditions of the exemption will be met. The Food and Drug Administration will be prepared to confer with the sponsor of the investigator, the investigator himself, or both, on this point.

(9) The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505(b) of the act, or give reasons for not submitting such application or a statement that the investigation has been discontinued and the reasons therefor:

(i) With reasonable promptness after finding that the results of such investigation appear to establish the safety and effectiveness of the drug; or

(ii) Within 60 days after receipt of a written request for such an application from the Commissioner.

(10) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the drug being distributed interstate for investigational use is safe or useful for the purposes for which it is under investigation. This regulation is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay communications media; its sole intent is to restrict promotional claims of safety or effectiveness by the sponsor while the drug is under investigation to establish its safety or effectiveness.

(11) The sponsor shall not commercially distribute nor test-market the drug until a new-drug application is approved pursuant to section 505(b) of the act.

(12) If the Commissioner of Food and Drugs finds that:

(i) The information submitted pursuant to subparagraph (1) of this paragraph contains an untrue statement of a material fact or omits material information required by said notice; or

(ii) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(iii) There is substantial evidence to show that the drug is unsafe for the purposes and in the manner for which it is offered for investigational use; or

(iv) There is convincing evidence that the drug is ineffective for the purposes for which it is offered for investigational use; or

(v) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drugs are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug; or

(vi) The clinical investigation of the drug described in subparagraph (1) of this paragraph is not reasonable in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe and effective for use; or

(vii) The clinical investigations are not being conducted in accordance with the information submitted pursuant to subparagraph (1)(i) of this paragraph; or

(viii) The drug is not intended solely for investigational use, since it is being or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(ix) The labeling or other informational material submitted for the drug as required by subparagraph (1)(ii) of this paragraph or any other labeling of the drug disseminated within the United States by or on behalf of the sponsor fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contraindications, side effects, and precautions; or any promotional material disseminated within the United States by or on behalf of the sponsor contains any representation or suggestions that the drug is safe

or that its usefulness has been established for the purposes for which it is offered for investigation; or

(x) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side effects, and precautions pertinent to the safety of the new drug:

He shall notify the sponsor and invite his immediate correction. A conference will be arranged if requested. If the conditions of the exemption are not immediately met, the Commissioner shall notify the sponsor of the termination of the exemption and the sponsor shall recall or have destroyed the unused supplies of the drug.

(13) No edible products derived from test animals are used for food purposes unless an authorization is obtained from the Food and Drug Administration. Requests for authorization to use edible products derived from test animals for food purposes shall be submitted in accordance with § 121.75 of this chapter.

(14) Where drugs were under clinical trial on animals on or after the effective date of this section the sponsor shall, within 30 days after the regulations in this section become effective, submit a list of such investigational drugs, and within 120 days after such effective date shall submit to the Food and Drug Administration the signed statement described in subparagraph (1) of this paragraph, or a new-drug application. Failure to do so shall automatically terminate the exemption. If any such clinical trials have been discontinued, the sponsor is requested to submit a statement of why the investigation was discontinued.

(c) A shipment or other delivery of a new drug that is being imported or is offered for importation into the United States shall be exempt from the requirements of section 505(a) of the act if the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to laboratory testing. Not for use in humans. Not for use in or on animals the products of which (meat, milk, eggs, etc.) are to be used for food," or the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use in animals. Food use of animal products derived from test animals prohibited without authorization under the Federal Food, Drug, and Cosmetic Act"; and

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has, prior to such shipments and deliveries in the case of new drugs for laboratory testing, informed the Food and Drug Administration of his intent to import the new drug and agreed in writing to maintain the records and otherwise comply with paragraph (a) of this section; or, in case of new drugs for clinical investigations, submitted a signed statement in accordance with paragraph (b)(1) of this section and acts as sponsor for the clinical investigations; or

(3) The drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct laboratory or clinical investigations and is intended solely for use in such institutions and there has been filed with the Food and Drug Administration the same information and agreement described in subparagraph (2) of this paragraph.

Dated: June 15, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 64-6068; Filed, June 18, 1964; 8:47 a.m.]

FEDERAL MARITIME COMMISSION

[46 CFR Part 536]

[Foreign Tariff Circular 1; Docket 964]

FILING OF TARIFFS BY COMMON CARRIERS BY WATER IN FOREIGN COMMERCE OF UNITED STATES AND BY CONFERENCES OF SUCH CARRIERS

Further Extension of Time for Filing Comments

On April 21, 1964, the Federal Maritime Commission published in the FEDERAL REGISTER (29 F.R. 5350) a notice of modification of proposed tariff filing rules and directed that all written statements, data, views, or arguments be submitted within 30 days of the date of publication. Time for submission was subsequently extended to June 22, 1964.

Upon request of various interested persons, and good cause appearing, the time for submission is further extended to the close of business on September 22, 1964.

By the Commission, June 11, 1964.

[SEAL] THOMAS LISI,
Secretary.

[F.R. Doc. 64-6099; Filed, June 18, 1964; 8:49 a.m.]

Notices

DEPARTMENT OF THE TREASURY

Bureau of Customs

[AA 643.3–b]

BEEF STEAKS FROM CANADA

Purchase Price Less Than Foreign Market Value

JUNE 16, 1964.

Pursuant to section 201(b) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(b)), notice is hereby given that there is reason to believe or suspect, from information presented to me, that the purchase price of 12/18-ounce beef steaks imported from Canada, produced by Holiday Farms Ltd., Chippawa, Ontario, Canada, is less, or likely to be less, than the foreign market value, as defined by sections 203 and 205 respectively, of the Antidumping Act, 1921, as amended (19 U.S.C. 162 and 164).

Customs officers are being authorized to withhold appraisement of entries of 12/18-ounce beef steaks from Canada, produced by Holiday Farms Ltd., Chippawa, Ontario, Canada, pursuant to § 14.9 of the Customs Regulations (19 CFR 14.9).

The allegation in this case was received on March 30, 1964, and was made by Freezer Queen Inc., Buffalo, New York.

[SEAL] PHILIP NICHOLS, Jr.,
Commissioner of Customs.

[F.R. Doc. 64–6090; Filed, June 18, 1964; 8:49 a.m.]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

ANCHORAGE LAND OFFICE

Change of Location and Temporary Closing

JUNE 17, 1964.

Notice is hereby given that the Anchorage Land Office, Bureau of Land Management, will be closed for business after 3:00 p.m., June 19, 1964 for the purpose of moving. It will be reopened for business at 10:00 a.m., June 23, 1964 in the Cordova Building, 555 Cordova Street, Anchorage, Alaska. In accordance with Title 43, Code of Federal Regulations 1821.2 applications and other documents received between the time the Land Office closes and 10:00 a.m. June 23, 1964 will be considered as filed at 10:00 a.m. June 23, 1964.

H. R. HOCHMUTH,
Associate Director.

[F.R. Doc. 64–6128; Filed, June 18, 1964; 8:52 a.m.]

[Oregon 0152440]

OREGON

Notice of Proposed Withdrawal and Reservation of Land

JUNE 12, 1964.

The Forest Service, United States Department of Agriculture, has filed an application, Serial No. Oregon 015240, for the withdrawal of the lands described below, from location and entry under the general mining laws, subject to valid existing rights.

The applicant desires a portion of the land for development of public outdoor recreation and general administration and to safeguard the government's investments in structures and improvements. Part of the withdrawal is requested to preserve a unique geological and archeological area. The lands are located in the Siskiyou National Forest.

For a period of 30 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the undersigned officer of the Bureau of Land Management, Department of the Interior, 710 NE. Holladay, Portland, Oregon, 97232.

The authorized officer of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demand for the lands and their resources. He will also undertake negotiations with the applicant agency with the view of adjusting the application to reduce the area to the minimum essential to meet the applicant's needs, to provide for the maximum concurrent utilization of the lands for purposes other than the applicant's, and to reach agreement on the concurrent management of the lands and their resources.

He will also prepare a report for consideration by the Secretary of the Interior who will determine whether or not the lands will be withdrawn as requested by the Forest Service.

The determination of the Secretary on the application will be published in the FEDERAL REGISTER. A separate notice will be sent to each interested party of record.

If circumstances warrant it, a public hearing will be held at a convenient time and place, which will be announced.

The lands involved in the application are:

OREGON

WILLAMETTE MERIDIAN

Siskiyou National Forest

Bear Camp Lookout and Campground

T. 34 S., R. 10 W.,
In sec. 12.
Total, 20 acres.

Lower Rogue River Recreational Area Addition

T. 34 S., R. 11 W.,
In sec. 19.
T. 35 S., R. 12 W.,
In sec. 29,
In sec. 30.
Total, 315.06 acres.

Johnson Mountain Lookout

T. 32 S., R. 12 W.,
In sec. 3.
Total, 5 acres.

Wildhorse Lookout

T. 36 S., R. 12 W., Unsurveyed,
In sec. 7.
Total, 5 acres.

Game Lake Peak Observation Site

T. 36 S., R. 12 W., Unsurveyed,
In sec. 26.
Total, 25 acres.

Snow Camp Lookout

T. 37 S., R. 12 W., Unsurveyed,
In sec. 30.
Total, 20 acres.

Tannen Ridge Observation Site

T. 41 S., R. 6 W.,
In sec. 16.
Total, 10 acres.

Big Pine Campground

T. 36, S., R. 8 W.,
In sec. 8.
Total, 50 acres.

Onion Mountain Lookout

T. 36 S., R. 8 W.,
In sec. 11.
Total, 10 acres.

Josephine Bridge Campground

T. 38 S., R. 8 W.,
In sec. 19.
Total, 14.86 acres.

Onion Campground

T. 38 S., R. 9 W.,
In sec. 30.
Total, 10 acres.

Bob's Garden Mountain Observation Site

T. 34 S., R. 10 W.,
In sec. 5.
Total, 20 acres.

Long Ridge Observation Site

T. 38 S., R. 12 W.,
In sec. 23.
Total, 9.68 acres.

Elk Lake Campground

T. 33 S., R. 13 W.,
In sec. 24,
In sec. 25.
Total, 20 acres.

Quosatana Geological and Archeological Area

T. 36 S., R. 13 W., Unsurveyed,
In sec. 27,
In sec. 33,

In sec. 34.
Total, 580 acres.

Pyramid Rock Observation Site

T. 37 S., R. 13 W., Unsurveyed,
In sec. 18,
In sec. 19.
Total, 10 acres.

The total combined area is 1,124.60 acres.

DOUGLAS E. HENRIQUES,
Manager, Land Office.

[F.R. Doc. 64-6059; Filed, June 18, 1964; 8:45 a.m.]

CALIFORNIA

Termination of Proposed Withdrawal and Reservation of Lands

JUNE 15, 1964.

The Forest Service, United States Department of Agriculture filed an application for withdrawal and reservation of lands serial number Riverside 0126, on January 2, 1962 (F.R. Doc. 62-1858). The applicant agency has canceled its application insofar as it involved the lands described below. Therefore, pursuant to the regulations contained in 43 CFR, Part 2310 (formerly 43 CFR, Part 295), such lands will be at 10:00 a.m. on Monday, July 27, 1964, relieved of the segregative effect of the abovementioned application.

The lands involved in this notice of termination are:

SAN BERNARDINO MERIDIAN, CALIFORNIA

T. 3 S., R. 1 W.,
Sec. 24, lots 1, 2, 3, 4, 5, 6, 7, 8, 9;
Sec. 28, E½NE¼, W½SE¼;
Sec. 32, SW¼SE¼.

JENS C. JENSEN,
Manager.

[F.R. Doc. 64-6093; Filed, June 18, 1964; 8:49 a.m.]

ATOMIC ENERGY COMMISSION

[Docket 70-855]

COLUMBIA UNIVERSITY, c/o INDUSTRIAL REACTOR LABORATORIES, INC.

Notice of Issuance of License

Notice is hereby given that the Atomic Energy Commission, on June 10, 1964 issued Special Nuclear Material License No. SNM-800 to Columbia University, % Industrial Reactor Laboratories, Inc. The license authorizes the transfer of irradiated fuel elements used in the reactor licensed under facility license R-46, from the site at Plainsboro, New Jersey to the Commission's Idaho Chemical Processing Plant. The shielded cask which will be used for this shipment was previously approved in connection with the issuance of License No. SNM-751, Docket No. 70-816. The shipments are to be made in accordance with the procedures described in the application dated April 10, 1964 as supplemented to date. For further details see (1) the application and (2) a Safety Analysis by the Irradiated Fuels Branch of the Division of Materials Licensing in Docket No. 70-855, both of which are on file at the AEC's Public Document Room. A copy of the Safety Analysis by the Irradiated Fuels Branch is available upon request addressed to the Atomic Energy Commission, Washington, D.C., 20545, Attention: Director, Division of Materials Licensing.

Dated at Bethesda, Md., this 10th day of June 1964.

For the Atomic Energy Commission.

LYALL JOHNSON,
Acting Director,
Division of Materials Licensing.

[F.R. Doc. 64-6075; Filed, June 18, 1964; 8:47 a.m.]

[Docket No. 50-57]

WESTERN NEW YORK NUCLEAR RESEARCH CENTER, INC.

Notice of Proposed Issuance of Facility License Amendment

Please take notice that the Atomic Energy Commission proposes to issue to Western New York Nuclear Research Center, Inc. ("the licensee"), an amendment to Facility License No. R-77 substantially in the form set forth below. The license authorizes the operation of the nuclear reactor facility located on the campus of the State University of New York at Buffalo, New York.

The proposed amendment would authorize the licensee to perform a test program on their uranium dioxide, rod-type core to demonstrate the ability of this core to be routinely pulsed to energy release levels of 40 Mw-sec and to proof test the core at energy release levels of 90 Mw-sec for a limited number of pulses. The proposed amendment was requested by the licensee in an application for license amendment dated September 27, 1963, including a revised Safety Analysis Report, Revision II, dated September 23, 1963. The licensee has also submitted additional amendments to the application dated January 14, 1964, February 18, 1964, February 26, 1964, March 17, 1964, April 9, 1964, April 15, 1964, April 21, 1964, May 28, 1964, and May 29, 1964.

The Commission has found that:

(1) The application for amendment complies with the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations set forth in title 10, Chapter 1, CFR;

(2) Operation of the facility in accordance with the license, as amended, will not present undue hazard to the health and safety of the public and will not be inimical to the common defense and security.

Within fifteen (15) days from the date of publication of this notice in the FEDERAL REGISTER, the applicant may file a request for a hearing, and any person whose interest may be affected by the proposed issuance of this amendment may file a petition for leave to intervene. A request for a hearing and petitions to intervene shall be filed in accordance with the provisions of the Commission's "Rules of Practice", 10 CFR Part 2. If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in this notice, a notice of hearing or an appropriate order will be issued. If no request for a hearing or a petition for leave to intervene is filed within the time prescribed in this notice, the Commission will issue the license amendment fifteen (15) days from the date of publication of this notice in the FEDERAL REGISTER.

For further details with respect to this proposed amendment, see (1) the application for license amendment dated September 27, 1963, including a revised Safety Analysis Report, Revision II, dated September 23, 1963, and supplements thereto dated January 14, 1964, February 18, 1964, February 26, 1964, March 17, 1964, April 9, 1964, April 15, 1964, April 21, 1964, May 28, 1964 and May 29, 1964, (2) a related hazards analysis prepared by the Research and Power Reactor Safety Branch of the Division of Reactor Licensing, and (3) the Technical Specifications for this experimental program designated as Section "P" of Appendix "A" to License No. R-77. These documents will be available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. A copy of the hazards analysis may be obtained at the Commission's Public Document Room, or upon request addressed to the Atomic Energy Commission, Washington, D.C., 20545, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Md., this 18th day of June 1964.

For the Atomic Energy Commission.

ROGER S. BOYD,
Chief, Research and Power Reactor Safety Branch, Division of Reactor Licensing.

[License No. R-77 Amdt. No.]

PROPOSED AMENDMENT TO FACILITY LICENSE

License No. R-77, as amended, which authorizes Western New York Nuclear Research Center, Inc., to operate the nuclear reactor facility located on the campus of the State University of New York at Buffalo, New York, is hereby further amended as follows:

Western New York Nuclear Research Center, Inc., is authorized to perform a test program on their uranium dioxide rod-type core to demonstrate the ability of this core to be routinely pulsed to energy release levels of 40 Mw-sec and to proof test the core at energy release levels of 90 Mw-sec for a limited number of pulses in accordance with its application for license amendment dated September 27, 1963, including a revised Safety Analysis Report, Revision II, dated September 23, 1963, and supplements thereto dated January 14, 1964, February 18, 1964, February 26, 1964, March 17, 1964, April 9, 1964, April 15, 1964, April 21, 1964, May 28, 1964, and May 29, 1964.

This amendment is effective as of the date of issuance.

For the Atomic Energy Commission.

ROGER S. BOYD,
Chief, Research and Power Reactor Safety Branch, Division of Reactor Licensing.

Date of issuance:

[F.R. Doc. 64-6197; Filed, June 18, 1964; 12:15 p.m.]

CIVIL AERONAUTICS BOARD

[Docket No. 13777; Order No. E-20941]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Agreement Adopted Relating to Specific Commodity Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 15th day of June 1964; Docket 13777; Agreement C.A.B. 17666 R–38 through R–41.

There has been filed with the Board, pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations an agreement between various air carriers, foreign air carriers, and other carriers, embodied in the resolutions of Traffic Conference 1 of the International Air Transport Association (IATA), and adopted pursuant to the provisions of Resolution 590 (Commodity Rates Board).

The agreement, adopted pursuant to unprotested notices to the carriers and promulgated in IATA memoranda, names additional rates as set forth below:

Agreement C.A.B. 17666	IATA memorandum TC1/ Rates	Commodity Item	Rates
R-38	1995	0070	13 cents per kilogram, minimum weight, 500 kilograms; San Juan to Port-au-Prince.
R-39	1996	1430	30 cents per kilogram, minimum weight, 100 kilograms; Port-au-Prince to New York—15 cents per kilogram, minimum weight, 100 kilograms; Port-au-Prince to Miami.
R-40	1997	4401	22 cents per kilogram, minimum weight, 200 kilograms; Panama City to Miami.
R-41	2000	0420	11 cents per kilogram, minimum weight, 1,000 kilograms; Guayaquil to Miami.

The Board, acting pursuant to sections 102, 204(a), and 412 of the Act, does not find the subject agreement to be adverse to the public interest or in violation of the Act, provided that approval thereof is conditioned as hereinafter ordered.

Accordingly, it is ordered:

That Agreement C.A.B. 17666, R–38, through R–41, be and hereby is approved, provided that such approval shall not constitute approval of the specific commodity descriptions contained therein for purposes of tariff publication.

Any air carrier party to the agreement, or any interested person, may, within 15 days from the date of service of this order, submit statements in writing containing reasons deemed appropriate, together with supporting data, in support of or in opposition to the Board's action herein. An original and nineteen copies of the statements should be filed with the Board's Docket Section. The Board may, upon consideration of any such statements filed, modify or rescind its action herein by subsequent order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] HAROLD R. SANDERSON, *Secretary.*

[F.R. Doc. 64–6107; Filed, June 18, 1964; 8:51 a.m.]

[Docket 14945; Order No. E–20942]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Agreement Adopted Relating to Specific Commodity Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 15th day of June 1964; Docket 14945; Agreement C.A.B. 17633 R–12 and R–13.

There has been filed with the Board, pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, an agreement between various air carriers, foreign air carriers, and other carriers, embodied in the resolutions of Joint Conference 1–2 of the International Air Transport Association (IATA), and adopted pursuant to the provisions of Resolution 590 (Commodity Rates Board).

The agreement, adopted pursuant to unprotested notices to the carriers and promulgated in IATA memoranda, names additional rates as set forth below:

Agreement C.A.B. 17633	IATA memorandum JT12/ Rates	Commodity Item	Rates
R-12	3079	4704	98/90 cents per kilogram; minimum weight, 200/500 kilograms, respectively; Prague to New York.
R-13	3804	4201	276/221 cents per kilogram; weight, 200/500 kilograms, respectively New York to Johannesburgh.

The Board, acting pursuant to sections 102, 204(a), and 412 of the Act, does not find the subject agreement to be adverse to the public interest or in violation of the Act, provided that approval thereof is conditioned as hereinafter ordered.

Accordingly, it is ordered:

That Agreement C.A.B. 17633, R–12 and R–13, be and hereby is approved, provided that such approval shall not constitute approval of the specific commodity descriptions contained therein for purposes of tariff publications.

Any air carrier party to the agreement, or any interested person, may, within 15 days from the date of service of this order, submit statements in writing containing reasons deemed appropriate, together with supporting data, in support of or in opposition to the Board's action herein. An original and nineteen copies of the statement should be filed with the Board's Docket Section. The Board may, upon consideration of any such statements filed, modify or rescind its action herein by subsequent order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] HAROLD R. SANDERSON, *Secretary.*

[F.R. Doc. 64–6108; Filed, June 18, 1964; 8:51 a.m.]

[Docket 14493]

EASTERN AIR LINES, INC.

Redesignation of Philadelphia, Pa.-Wilmington, Del.; Notice of Hearing

Notice is given herewith, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled proceeding will be held before the undersigned Examiner on July 13, 1964 at 10:00 a.m., e.d.s.t., in the Court of Chancery, Courtroom Number 2, Eleventh and King Streets, Wilmington, Delaware.

For information concerning the issues and other details in this proceeding, interested persons are referred to the Prehearing Conference Report served on May 21, 1964, and other documents which are on file in this proceeding in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., May 15, 1964.

[SEAL] RICHARD A. WALSH, *Hearing Examiner.*

[F.R. Doc. 64–6109; Filed, June 18, 1964; 8:52 a.m.]

[Tucson-Albuquerque Service, Order E–20912; Docket 5395 etc.]

REOPENED SOUTHERN ROCKY MOUNTAIN AREA SERVICE CASE

Notice of Prehearing Conference

Notice is hereby given that a prehearing conference in the above-entitled matter is assigned to be held on July 1, 1964, at 10 a.m., e.d.s.t., in Room 725, Universal Building, Connecticut and Florida Avenues NW., Washington, D.C., before Examiner Thomas L. Wrenn.

Dated at Washington, D.C., June 16, 1964.

[SEAL] FRANCIS W. BROWN, *Chief Examiner.*

[F.R. Doc. 64–6110; Filed, June 18, 1964; 8:52 a.m.]

[Docket 13890]

SUSPENSION OF STANDARD AIRWAYS' INTERIM CERTIFICATE

Notice of Prehearing Conference

Notice is hereby given that a prehearing conference in the above-entitled matter is assigned to be held on July 7, 1964, at 10 a.m., e.d.s.t., in Room 725, Universal Building, Connecticut and Florida Avenues NW., Washington, D.C., before Associate Chief Examiner Thomas L. Wrenn.

Dated at Washington, D.C., June 16, 1964.

[SEAL] FRANCIS W. BROWN,
Chief Examiner.

[F.R. Doc. 64-6111; Filed, June 18, 1964; 8:52 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 15471; FCC 64M-540]

AMERICAN TELEPHONE AND TELEGRAPH CO.

Statement and Order After Prehearing Conference

In the matter of American Telephone and Telegraph Company, Docket No. 15471; charges for special construction over other than normal routes.

At the prehearing conference of June 12, 1964, among other things the following schedule was agreed upon:

A.T. & T. to furnish direct affirmative written case by: September 14, 1964.
Hearing: Tuesday, September 29, 1964, at 10 a.m. (rescheduled from July 8, 1964).

Sponsors of the written case will be present for cross-examination.

So ordered, this 15th day of June 1964.

Released: June 15, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-6102; Filed, June 18, 1964; 8:50 a.m.]

[Docket Nos. 15289, 15290; FCC 64M-531]

C & G ELECTRONICS CO. AND RADIOFONE SERVICE

Order Continuing Hearing

In re applications of C & G Electronics Company, Docket No. 15289, File No. 216-C2-P-63, for a construction permit to establish new facilities in the Domestic Public Land Mobile Radio Service at Tacoma, Washington; Robert M. Kunz, d/b as Radiofone Service, Docket No. 15290, File No. 1167-C2-P-63, for a construction permit to modify the facilities of Station KOE518 in the Domestic Public Land Mobile Radio Service at Tacoma, Washington.

Upon the verbal request by counsel for C & G Electronics Company, and with good cause being disclosed: *It is ordered,* This 11th day of June 1964, that the hearing herein now scheduled for June 12, 1964, be and the same is hereby continued to July 10, 1964, 10:00 a.m., in the Commission's office, Washington, D.C.

Released: June 12, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-6103; Filed, June 18, 1964; 8:50 a.m.]

[Docket Nos. 15436, 15437; FCC 64M-532]

SKYLARK CORP. AND KINGSTON BROADCASTERS, INC.

Order Continuing Hearing

In re applications of Skylark Corporation, Kingston, New York, Docket No. 15436, File No. BPH-4256; Kingston Broadcasters, Inc., Kingston, New York, Docket No. 15437, File No. BPH-4357; for construction permits.

The Hearing Examiner having under consideration the change of date for commencement of hearing;

It appearing, that because of the illness of a principal in one of the applicants and for other reasons discussed off the record at a prehearing conference on this date, good cause has been shown for changing the date for commencement of hearing which is now scheduled as July 7, 1964;

It is ordered, This 11th day of June 1964, that the date for commencement of hearing is changed from July 7 to September 22, 1964.

Released: June 12, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-6104; Filed, June 18, 1964; 8:50 a.m.]

[Docket Nos. 15460, 15461; FCC 64M-533]

SYMPHONY NETWORK ASSOCIATION, INC., AND CHAPMAN RADIO AND TELEVISION CO.

Order Continuing Hearing

In re applications of Symphony Network Association, Inc., Fairfield, Alabama, Docket No. 15460, File No. BPCT-3238; William A. Chapman and George K. Chapman, d/b as Chapman Radio and Television Company, Homewood, Alabama, Docket No. 15461, File No. BPCT-3282; for construction permits for a new television broadcast station.

A prehearing conference having been held on June 11, 1964, and it appearing from the record made therein that certain agreements were reached and certain rulings made which should be formalized by order:

It is ordered, This 11th day of June 1964, that:

(1) The direct affirmative cases of the applicants shall be presented primarily in the form of sworn, written exhibits, but the applicants shall have the right to supplement their written cases by oral testimony subject to the provisions of paragraph (4), infra;

(2) Copies of the applicants' exhibits shall be exchanged on or before July 13, 1964; provided that the said exhibits may be modified through July 20, 1964, by the correction of errors, by the addition of material requested by the other parties, or by the addition of material necessary to satisfy the designated issues, but are not to be modified by the addition of substantial new material designed to improve the applicant's showing vis-a-vis its opponent;

(3) Copies of the applicants' exhibits in final form shall be exchanged on or before July 20, 1964;

(4) In the event either applicant proposes to supplement its written case with oral testimony, such applicant shall, on or before July 20, 1964, furnish all other parties information as to the identity of such witnesses and the general scope of their testimony; and,

(5) Any party wishing to call for cross-examination any witness sponsoring another party's exhibit shall give notification thereof on or before July 24, 1964:

It is further ordered, That the hearing now scheduled to commence on July 15, 1964, is continued to July 27, 1964, commencing at 10:00 a.m. in the offices of the Commission at Washington, D.C.

Released: June 12, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-6105; Filed June 18, 1964; 8:51 a.m.]

[Docket No. 15502, FCC 64-528]

PROGRESS VALLEY BROADCASTERS CO.

Memorandum Opinion and Order Designating Matter for Oral Argument on Specified Issue

In re matter of assignment of call letters KISM to Progress Valley Broadcasters Company's new standard broadcast station at Shakopee, Minnesota, Docket No. 15502.

1. The Commission has before it for consideration (a) informal pleading dated October 2, 1963, by Southern Minnesota Supply Company (Southern) licensee of standard broadcast station KYSM, Mankato, Minnesota, requesting Commission action to require Progress Valley Broadcasters Company (Progress Valley), permittee of standard broadcast station KISM, Shakopee, Minnesota, to change its call letters; (b) Progress Valley's October 15, 1963, informal opposition; (c) "Petition to Designate for Hearing" Progress Valley's license application (File No. BL-10337) filed by Southern November 7, 1963; (d) Progress Valley's November 20, 1963 "Opposition to Petition to Designate for Hearing"; and related correspondence.

2. On June 27, 1963, the Commission granted Progress Valley's application (File No. BP-14665) for authority to construct a new daytime standard broadcast station at Shakopee, Minnesota (1530 kc/s, 500 watts). On August 14, 1963 the call letters KISM, which Progress Valley had earlier requested, were assigned. Progress Valley completed construction and filed its application (File No. BL-10337) for covering license on September 27, 1963. Pending further action on this application, the Commission, on October 4, 1963 authorized Progress Valley to commence program test operation.

3. Although the call letters were assigned on August 14, 1963, Southern did not file its informal objection until Octo-

ber 2, 1963. According to Southern, this objection was filed immediately after it became aware of the assignment, the absence of a public notice requirement for call letter requests and assignments having precluded timely objection. On the merits, Southern asserts that there is significant overlap of the stations' respective interference-free primary service contours;[1] that there is a marked phonetic and rhythmic similarity between the respective call letters; and consequently that there is a great likelihood of public confusion. Southern cites John Poole Broadcasting Co., Inc. 25 R.R. 335 (1963) and Radio Virginia, Inc. (unreported Commission letter of May 14, 1947) in support of its view that these facts warrant a change in call letters.

4. Progress Valley's informal opposition, filed October 15, 1963, insists that Southern's pleading can not be considered as a petition for reconsideration since it was not filed within thirty days after Commission action, as required by section 405 of the Act and § 1.106(f)—formerly § 1.84(f)—of the rules. Progress Valley contends that the pleading, therefore, must be considered as a request that the Commission proceed under section 316 of the Act to modify Progress Valley's permit, thus entitling it to be heard in an evidentiary hearing, citing KPOI Broadcasting Co., Inc. 18 R.R. 985 (1959). Further, Progress Valley urges that such action is not justified by the existence of "fringe" overlap of the respective interference-free 0.5 mv/m contours. This overlap, it says, should not obscure the fact that the stations are approximately fifty miles apart; that they serve basically different areas; that as a Shakopee station, KISM orients its programming and promotional activities in the direction of Shakopee-Chasta and the nearby twin-cities, while KYSM addresses its programming to the rural area in the vicinity of Mankato; that KISM operates daytime only, while KYSM operates unlimited time; and that the stations are well separated on the dial—1230 kc/s v. 1530 kc/s. Progress Valley asserts that Southern's reliance on *Poole* and *Radio Virginia* is misplaced since, notwithstanding their assignment to different cities, the Commission found that they served essentially the same areas, a situation it insists is absent in the present case. Progress denies having knowledge of any specific instance of public confusion and, in addition, argues that any isolated instances of confusion which might have occurred would be insufficient to warrant Commission action.

5. On November 7, 1963 Southern supplemented its earlier objection with a formal petition to designate for hearing Progress Valley's pending license application (File No. BL–10337). In addition to reiterating many of its previous arguments, Southern states that for 25 years KYSM has used the catch-word "KISS–M" in over-the-air station promotions, a practice which it alleges KISM has adopted. Southern argues that this practice has created considerable public confusion, as shown by the number of listeners who have called the station asking about the similar sets of call letters. Southern further contends that call letter confusion is a "cause or circumstance arising or first coming to the knowledge of the Commission since the granting of the permit * * * (which makes) the operation of such station against the public interest"; hence, that Progress Valley's license application must be designated for hearing pursuant to section 319(c) of the Communications Act and § 1.68(a) of the rules. Alternatively, Southern urges adoption of an Order to Show Cause why Progress' permit should not be modified, or grant of the license application conditioned upon relinquishment of the call letters.

6. Progress Valley's opposition filed on November 20, 1963, argues that Southern's petition seeks to circumvent the 30-day time limit for filing petitions for reconsideration, and that in any event Southern has offered no new matters warranting a hearing on Progress Valley's license application. Moreover, Progress Valley asserts that the alleged similarity of the stations' promotional techniques would only assume importance if, unlike the present situation, the stations served the same area and in any event that its slogan "Don't miss'em, dial kiss'm" is given only occasional exposure over the air. Progress Valley also points out that Southern has alleged no cases of actual confusion, but referred instead to listeners who have called the station to inquire about the similarity in call letters, thus demonstrating that notwithstanding the similarity, listeners are clearly able to differentiate between the two stations. Progress Valley concludes that any action against it would be unwarranted, would prejudice the substantial investment made in reliance on assignment of the call letters, and that changing the call letters of an operating station might well create confusion where none existed before.

7. As we stated in Poole, supra, * * * (T)he applicable principle is that stations may use call letters of their choice, excepting the initial letter, if the requested call letters are available and in good taste and (are) sufficiently dissimilar phonetically and rhythmically from the existing call letters of stations of the same service in the area, so that there will be no significant likelihood of public confusion resulting," (emphasis supplied) 25 R.R. 335 at 336. In both Radio Virginia and Poole, supra, the Commission looked beyond mere station location and determined that they served substantially the same area. Admittedly, the fact that stations have different locations can, in certain circumstances, be an element in negativing the likelihood of confusion—Pittsburg Broadcasting Company, 4 R.R. 1234 (1949). On the other hand it must be recognized that confusion is likely to occur where the stations involved serve significant areas in common. Obviously, as distance increases and overlap of service areas decreases, the factors distinguishing the stations assume progressively greater importance. Although no precise line can be drawn, we believe that a prima facie case of public confusion obtains where there is substantial overlap of primary service areas between stations with phonetically similar call letters. In this connection, 10 percent of KYSM's 0.5 mv/m contour is overlapped by KISM, and approximately 60 percent of KISM's 0.5 mv/m contour is overlapped by KYSM.

8. The call letters in question are not only rhythmically and phonetically similar, but are promoted, over the air and otherwise, in a similar manner. Progress Valley argues that other factors are sufficient to offset these similarities and make confusion unlikely; for example, the audience toward which the programing of the two stations is directed is quite different. However, it has not shown how this alleged difference is reflected in the broadcasting of any particular programs by either station. Progress Valley also observes that the stations are well separated—1230 kc/s v. 1530 kc/s—however both are at the high end of the dial where the separation is least noticeable. On balance, we conclude that Southern has made a threshold showing that the listening public in a substantial area of overlap is apt to be confused by the continued use of the call letters KISM by Progress Valley.

9. Because call letters are assigned after grant of a permit, any question concerning the propriety of such an assignment is a matter * * * "arising or first coming to the knowledge of the Commission since the granting of the permit * * *"—47 USC 319(c). However, it does not follow that Progress Valley's pending license application must be designated for evidentiary hearing.

10. Our basic authority for assigning call letters is contained in section 303(o) of the Communications Act which simply states that the Commission shall "have authority to designate call letters of all stations". We have consistently held that the assignment of call letters is not subject to the general application procedures governing station licenses and permits—United Television, Inc. 14 R.R. 573 (1956); Valley Broadcasting Company (KWOW) 13 R.R. 208(a) (1955). Call letters are, in fact, assigned after grant of the original construction permit, on the basis of preferences expressed by the permittee, and for the sole purpose of station identification. It follows that an ordered change in call letters does not work a modification of permit within the meaning of section 316 of the Act, and that no right to hearing is conferred thereby.

11. Although we recognize no proprietary interest in call letters, equity demands that requests for their withdrawal receive our most careful prior consideration. In Poole, supra, the Court of Appeals, upon representations of irreparable injury, stayed further Commission action "* * * pending an opportunity for such hearing and decision as the Commission may see fit to take * * *"

[1] Southern also claims that increased overlap would be created by grant of its pending application (File No. BP–13346) for change in frequency and power increase. Admittedly, this would be so. However that application is mutually exclusive with another proposal and, in any event, does not offer a proper basis for deciding the present dispute.

Thus, whatever possibility of summary action changing call letters exists in the abstract, where in situations of this type there has been reliance on the assignment, fairness dictates that some form of hearing be provided. We do not read Poole as requiring that this hearing take any particular form. In this case, we believe that the holding of an oral argument, as was done in Poole, would satisfy the requirements of due process. Not only has Progress Valley failed to offer any persuasive justification for holding an evidentiary hearing, but, since further delay would work an injustice on both parties, oral argument clearly seems preferable.

In view of the foregoing: *It is ordered,* That pursuant to section 5(d) of the Communications Act the above-entitled matter is designated for oral argument before the Review Board in Washington, D.C. at a time to be specified by subsequent Order on the following issue: To determine whether Progress Valley Broadcasters Company should be required to relinquish the call letters KISM currently assigned to its standard broadcast station at Shakopee, Minnesota.

It is further ordered, That Southern Minnesota Supply Company is made a party to the proceeding.

It is further ordered, That further action on Progress Valley's application for station license (File No. BL–10337) shall be withheld pending the outcome of oral argument.

It is further ordered, That to avail themselves of the opportunity to be heard, the parties hereto, in person or by attorney, shall, within 20 days of the mailing of this order, file with the Commission, an original and 19 copies of a written appearance stating an intention to appear on the date fixed for the Oral Argument and present evidence on the issue specified in this order, and shall have until 10 days prior to Oral Argument to file briefs or memoranda of law.

Adopted: June 10, 1964.

Released: June 16, 1964.

FEDERAL COMMUNICATIONS COMMISSION,[2]
BEN F. WAPLE,
Secretary.

[F.R. Doc. 64–6106; Filed, June 18, 1964; 8:51 a.m.]

FEDERAL MARITIME COMMISSION

A. H. BULL & CO. ET AL.

Independent Ocean Freight Forwarder Applications

Notice is hereby given of changes in the following applications for independent ocean freight forwarder licenses issued pursuant to section 44, Shipping Act, 1916 (75 Stat. 522 and 46 U.S.C. 841 (b)).

[2] Commissioner Bartley absent; Commissioner Ford dissenting.

GRANDFATHER APPLICANTS

Name and address

Bull & Co., A. H., No. 376, 115 Broad Street, New York, N.Y., 10004; Revoked 5–5–64.

Bull-Insular Line of Puerto Rico, Inc., No. 376, P.O. Box 4435, San Juan, P.R.; Revoked 5–5–64.

Fitzgerald Forwarding Corp., No. 257, 40 West 32d Street, New York, N.Y., 10001; Revoked 5–15–64.

Traffic Co-Ordinators, Inc., No. 264, 43 Clarkson Street, New York, N.Y., 10014; Revoked 5–5–64.

NON-GRANDFATHER APPLICANTS

Name and address

Strickland Exporters and Finance Corp., 14 Northeast First Avenue, Miami, Fla.; Denied 5–1–64.

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission, applications for licenses as independent ocean freight forwarders, pursuant to section 44(a) of the Shipping Act, 1916 (75 Stat. 522 and 46 U.S.C. 841(b)).

Persons knowing of any reason why any applicant should not receive a license are requested to communicate with the Director, Bureau of Domestic Regulation, Federal Maritime Commission, Washington, D.C., 20573. Protests received within 60 days from the date of publication of this notice in the FEDERAL REGISTER will be considered.

Arrow International (Non) (Niberto Moreno, d/b/a), 1005 West 27th Avenue, Miami, Fla.; Niberto Moreno, owner.

Fast Delivery Service, Inc. (Non) (Enrique Radillo, d/b/a), Ave 65 de Infanteria, esquina a TTE., Alides Reyes, Rio Piedras, P.R.; Enrique Radillo, owner.

Helm's International, Inc. (Non), 1010 Lincoln Highway West, Irwin, Pa.; Harry M. Werksman, president and director; Dante J. Casali, vice president and director; Lawrence E. Ratermann, treasurer; Martin W. Snow, assistant treasurer; Samuel P. Delisi, secretary.

Marquette, William J. (Non), 111 Lawrence Place, New Rochelle, N.Y.; William J. Marquette, owner.

Transco International, Inc. (Late), 109 West 27th Street, New York, N.Y., 10001; Anthony Gonzalez, president/treasurer and director; Edna Gonzalez, vice president/secretary and director.

NAME CHANGES

Vairon & Co., Inc., No. 483, to Common Market Forwarders, Inc., 17 Battery Place, New York, N.Y., 10004; Rene G. Baisier, president/secretary; Henry E. Marcuse, vice president/treasurer.

Wall Shipping Co., Inc., No. 644, to Vanguard Shipping Co., 1007 Garrett Building, Baltimore, Md., 21202; Frank R. Bailey, president, treasurer and director; Robert W. Berberich, vice president and director; Martin J. McNamara, secretary and director.

NUMBER CHANGES

Footner and Co., Inc., No. 10 (previous No. 11), 5 South Street, Baltimore 2, Md.

H. W. St. John & Co., No. 1012 (previous No. 11), 44 Beaver Street, New York, N.Y., 10004.

A. E. Nydegger Co., Inc., No. 894 (previous No. 969), 10 Bridge Street, New York, N.Y., 10004.

Dated: June 15, 1964.

THOMAS LISI,
Secretary.

[F.R. Doc. 64–6100; Filed, June 18, 1964; 8:50 a.m.]

FEDERAL POWER COMMISSION

[Docket G–19495]

MISSISSIPPI RIVER FUEL CORP.

Notice of Application To Amend

JUNE 12, 1964.

Take notice that on April 27, 1964, Mississippi River Fuel Corporation (Mississippi River), 9900 Clayton Road, St. Louis, Missouri, 63124, filed in Docket No. G–19495, an application to amend an order of the Commission issued January 10, 1960, in Docket No. G–19495, which as presently amended, authorizes among other things the installation and operation of 19 compressor units consisting of a total of 5459 Hp on its gathering system in the Woodlawn Field, Harrison County, Texas. Mississippi River is now seeking authorization to install and operate an additional 675 Hp on its gathering system during 1964, all as more fully set forth in the application to amend on file with the Commission, and open to public inspection.

The application reflects the additional 675 Hp compressor capacity is required because of the continued decline in pressure in the field, and to enable Mississippi River to receive gas from the dedicated reserves. The estimated cost of the additional facilities is $120,000, which will be financed from cash on hand.

Protests, petitions to intervene or requests for hearing in this proceeding may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before July 6, 1964.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64–6085; Filed, June 18, 1964; 8:48 a.m.]

[Docket CP64–237]

TRANSWESTERN PIPELINE CO.

Notice of Application

JUNE 12, 1964.

Take notice that on April 14, 1964, as amended on June 1, 1964, Transwestern Pipeline Company (Applicant), First City National Bank Building, Houston, Texas, 77002, filed in Docket No. CP64–237 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction during the calendar year 1964 and the operation of routine field facilities to enable Applicant to take into its certificated main pipeline system natural gas which will be purchased from producers thereof, all as more fully set forth in the application and amendment which are on file with the Commission and open to public inspection.

The purpose of this "budget-type" application is to augment Applicant's ability to act with reasonable dispatch in contracting for and connecting to its pipeline system new supplies of natural gas in various producing areas generally coextensive with said system.

The total cost of the facilities covered by this application will not exceed a maximum of $1,000,000, with no single project to exceed a cost of $250,000, which costs are proposed to be financed from funds made available by company operations.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations and to that end:

Take further notice that preliminary staff analysis has indicated that there are no problems which would warrant a recommendation that the Commission designate this application for formal hearing before an examiner and that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing may be held without further notice before the Commission on this application provided no protest or petition to intervene is filed within the time required herein. Where a protest or petition for leave to intervene is timely filed, or where the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before July 6, 1964.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-6086; Filed, June 18, 1964; 8:48 a.m.]

[Project 2462]

VIRGINIA ELECTRIC AND POWER CO.

Notice of Application for License

JUNE 12, 1964.

Public notice is hereby given that application has been filed under the Federal Power Act (16 U.S.C. 791a-825r) by Virginia Electric and Power Company (correspondence to: Mr. R. M. Hutcheson, Senior Vice President, Virginia Electric and Power Company, 7th and Franklin Streets, Richmond 9, Virginia) for license for constructed Project No. 2462, known as the Belle Isle Project, located in the City of Richmond, on the James River in Henrico County, Virginia.

The Project consists of: (1) An 1,870 foot long concrete diversion dam; (2) a headrace formed by Belle Isle on the north, a 470 foot long masonry and concrete dam joined to a 74 foot long powerhouse on the south and enclosed on the lower end by a 138 foot long concrete dam; (3) a powerhouse containing three identical horizontal shaft units rated at 1,000 kw each for a total output of 3,000 kw; (4) a substation including a 4 kv bus and a 13.2 kv bus; and (5) appurtenant electrical and mechanical facilities.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure of the Commission (18 CFR 1.8 or 1.10). The last day upon which protests or petitions may be filed is August 7, 1964. The application is on file with the Commission for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-6087; Filed, June 18, 1964; 8:48 a.m.]

[Project 2463]

VIRGINIA ELECTRIC AND POWER CO.

Notice of Application for License

JUNE 12, 1964.

Public notice is hereby given that application has been filed under the Federal Power Act (16 U.S.C. 791a-825r) by Virginia Electric and Power Company (correspondence to: Mr. R. M. Hutcheson, Senior Vice President, Virginia Electric and Power Company, 7th and Franklin Streets, Richmond 9, Virginia) for license for constructed Project No. 2463, known as the Park Hydroelectric Project, located in the City of Richmond, on the James River in Henrico County, Virginia.

The project consists of: (1) A short headrace from the lower level of the Chesapeake and Ohio Canal which parallels the James River from its beginning at Bosher's Dam to its end immediately downstream from the Park Hydroelectric Project; (2) a short penstock connecting the headrace to the scroll case; (3) a concrete powerhouse containing one generating unit rated at 2,100 kilowatts; and (4) appurtenant electrical and mechanical facilities.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure of the Commission (18 CFR 1.8 or 1.10). The last day upon which protests or petitions may be filed is August 7, 1964. The application is on file with the Commission for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-6088; Filed, June 18, 1964; 8:49 a.m.]

SECURITIES AND EXCHANGE COMMISSION

[File 70-4219]

NEW JERSEY POWER & LIGHT CO.

Notice of Proposed Issuance and Sale of Principal Amount of Debentures at Competitive Bidding

JUNE 15, 1964.

Notice is hereby given that New Jersey Power & Light Company ("NJP&L"), Madison Avenue at Punch Bowl Road, Morristown, New Jersey, an electric utility subsidiary company of General Public Utilities Corporation ("GPU"), a registered holding company, has filed an application with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating section 6(b) of the Act and Rule 50 promulgated thereunder as applicable to the proposed transaction. All interested persons are referred to the application, on file at the office of the Commission, for a statement of the transaction therein proposed which is summarized below.

NJP&L proposes to issue and sell, subject to the competitive bidding requirements of Rule 50 promulgated under the Act, $6,000,000 principal amount of Debentures, __% Series due 1989. The interest rate of the debentures (which shall be a multiple of ⅛ of 1 percent) and the price, exclusive of accrued interest, to be paid to NJP&L (which shall be not less than 100 percent nor more than 102¾ percent of the principal amount thereof) will be determined by the competitive bidding. The debentures will be issued under an Indenture to be dated as of July 1, 1964, between NJP&L and The Chase Manhattan Bank, Trustee.

The proceeds (other than premium, if any, and accrued interest) from the sale of the debentures, together with a $3,000,000 cash contribution to be made to NJP&L by its parent company, GPU, (File No. 70-4212), will be used to finance construction expenditures and to pay short-term notes due banks, the proceeds of which were used for such purpose. At March 31, 1964, such short-term notes were outstanding in the amount of $5,820,000. Any premium from sale of the debentures will be used for general corporate purposes, including payment of expenses of the proposed financing program. NJP&L's 1964 construction program provides for expenditures of approximately $7,830,000.

Fees and expenses of the proposed financing are estimated at $55,000, and include legal fees of $10,500 and auditors fees of $3,500. The fees and disbursements of counsel for the underwriters, to be paid by the successful bidder, will be supplied by amendment.

The application states that the issue and sale of the debentures are subject to the jurisdiction of the Board of Public Utility Commissioners of the State of New Jersey, the State commission of the State in which NJP&L is organized and doing business. It is further stated that no other State commission and no Federal commission, other than this Commission, has jurisdiction over the proposed transaction.

Notice is further given that any interested person may, not later than July 9, 1964, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C., 20549. A copy of such request should be served personally or by mail (air mail if the

person being served is located more than 500 miles from the point of mailing) upon the applicant at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed contemporaneously with the request. At any time after said date, the application, as filed or as it may be amended, may be granted as provided in Rule 23 of the general rules and regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate.

For the Commission (pursuant to delegated authority).

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F.R. Doc. 64-6081; Filed, June 18, 1964; 8:48 a.m.]

INTERSTATE COMMERCE COMMISSION

FOURTH SECTION APPLICATIONS FOR RELIEF

JUNE 16, 1964.

Protests to the granting of an application must be prepared in accordance with Rule 1.40 of the general rules of practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

LONG-AND-SHORT HAUL

FSA No. 39080: *Soda ash to Hillsboro and Tampa, Fla.* Filed by Southwestern Freight Bureau, agent (No. B-8557), for interested rail carriers. Rates on soda ash, in carloads, from Corpus Christi, Freeport, and Houston, Tex., to Hillsboro and Tampa, Fla.

Grounds for relief: Market competition.

Tariff: Supplement 34 to Southwestern Freight Bureau, agent, tariff I.C.C. 4534.

FSA No. 39081: *Liquefied chlorine gas to St. Marys, Ga.* Filed by O. W. South, Jr., agent (No. A4527), for interested rail carriers. Rates on liquefied chlorine gas, in tank carloads, from Memphis, Tenn., to St. Marys, Ga.

Grounds for relief: Market competition.

Tariff: Supplement 175 to Southern Freight Association, agent, tariff I.C.C. S-116.

FSA No. 39082: *Liquid caustic soda to Coosa Pines, Ala.* Filed by O. W. South, Jr., agent (No. A4528), for interested rail carriers. Rates on liquid caustic soda, in tank carloads, from Calvert, Ky., to Coosa Pines, Ala.

Grounds for relief: Market competition.

Tariff: Supplement 175 to Southern Freight Association, agent, tariff I.C.C. S-116.

FSA No. 39083: *Lime to points in southern territory.* Filed by Illinois Freight Association, agent (No. 252), for interested rail carriers. Rates on lime, common, hydrated, quick or slaked, in carloads, from Hannibal, Mo., also Marblehead and Quincy, Ill., to specified points in southern territory.

Grounds for relief: Motor-carrier competition.

Tariffs: Supplements 89 and 261 to Illinois Freight Association, agent, tariffs I.C.C. 979 and 776, respectively.

FSA No. 39084: *Joint motor-rail rates—Eastern Central.* Filed by The Eastern Central Motor Carriers Association, Inc., agent (No. 265), for interested carriers. Rates on various commodities moving on class and commodity rates over joint routes of applicant rail and motor carriers, between points in central States, middlewest and southwestern territories, on the one hand, and points in middle Atlantic and New England territories, on the other.

Grounds for relief: Motortruck competition.

Tariff: 11th revised page 47-A to Eastern Central Motor Carriers Association, Inc., agent, tariff MF-I.C.C. A-230.

FSA No. 39085: *Joint motor-rail rates—Eastern Central.* Filed by The Eastern Central Motor Carriers Association, Inc., agent (No. 266), for interested carriers. Rates on various commodities moving on class and commodity rates over joint routes of applicant rail and motor carriers, between points in central States territory, on the one hand, and points in middle Atlantic and New England territories, on the other.

Grounds for relief: Motortruck competition.

Tariff: 4th revised page 118-A to Eastern Central Motor Carriers Association, Inc., agent, tariff MF-I.C.C. A-230.

FSA No. 39086: *Joint motor-rail rates—Eastern Central.* Filed by The Eastern Central Motor Carriers Association, Inc., agent (No. 268), for interested carriers. Rates on various commodities moving on class and commodity rates over joint routes of applicant rail and motor carriers, between points in central States territory, on the one hand, and points in middle Atlantic and New England territories, on the other.

Grounds for relief: Motortruck competition.

Tariff: 11th revised page 47-A to Eastern Central Motor Carriers Association, Inc., agent, tariff MF-I.C.C. A-230.

FSA No. 39087: *Newsprint paper to points in California.* Filed by Pacific Southcoast Freight Bureau, agent (No. 250), for interested rail carriers. Rates on newsprint paper, in carloads, from Crofthill and Duncan Bay, British Columbia, also St. Helen's and Wauna, Oreg., to points in California.

Grounds for relief: Market competition.

Tariffs: 14th, 8th, 18th, 19th and 8th revised pages 415G, 415GG, 415HH, 415J and 415K, respectively, to Pacific Southcoast Freight Bureau, agent, tariff I.C.C. 1352.

FSA No. 39088: *Class and commodity rates from and to Dune Park, Baileytown, and Burns Harbor, Ind.* Filed by Illinois Freight Association, agent (No. 253), for interested rail carriers. Rates on various commodities moving on class and commodity rates, in carloads and less-than-carloads, from or to Dune Park, Baileytown, and Burns Harbor, Ind., on the one hand, and from or to points in the United States and Canada, on the other.

Grounds for relief: New stations and groupings.

By the Commission.

[SEAL] HAROLD D. MCCOY, *Secretary.*

[F.R. Doc. 64-6070; Filed, June 18, 1964; 8:47 a.m.]

[Notice 1000]

MOTOR CARRIER TRANSFER PROCEEDINGS

JUNE 16, 1964.

Synopses of orders entered pursuant to section 212(b) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 179), appear below:

As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings within 20 days from the date of publication of this notice. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC 66890. By order of June 12, 1964, the Transfer Board approved the transfer to A. Sydney DeVos and Wray Fullerton, a partnership, doing business as McDonald Express and Transfer, McDonald, Pa., of the operating rights in Certificate in No. MC 96841 (Sub-No. 1), issued April 16, 1964, to Donald A. Poskin and Graves Birnie, doing business as McDonald Express and Transfer, McDonald, Pa., authorizing the transportation, over regular and irregular routes of: General commodities, except classes A and B explosives, but including household goods, and certain other specified commodities namely; coal, and oil well machinery and supplies, between specified points and areas in Pennsylvania. Frank C. Roney, 63 South Main Street, Washington, Pa., attorney for applicants.

No. MC-FC 66913. By order of June 12, 1964, the Transfer Board approved the transfer to Industrial Trucking Service Corporation, Penns Park, Pa., of the operating rights issued by the Commission May 5, 1958, under Certificate in No. MC 76109, to Rudolph Kraus, doing business as Industrial Trucking Service, Croydon, Pa., authorizing the transportation, over irregular routes, of such bulk commodities as are transported in dump trucks, between points in Philadelphia, Delaware, Chester, Bucks, and Montgomery Counties, Pa., on the one hand, and, on the other, points in New Jersey. V. Baker Smith, c/o Morgan, Lewis & Bockius, 2107 Fidelity-Philadelphia Trust Building, Philadelphia 9, Pa., attorney for applicants.

No. MC-FC 66916. By order of June 12, 1964, the Transfer Board approved

the transfer to Central Bergen Warehouse, Inc., Edgewater, N.J., of the operating rights in Certificate in No. MC 1183, issued November 21, 1956, to Central Freight Trucking, Inc., Edgewater, N.J., authorizing the transportation, over irregular routes, of general commodities, excluding household goods, commodities in bulk other than liquids, and other specified commodities, between points in the New York, N.Y., commercial zone, on the one hand, and, on the other, points in New York, New Jersey, and Connecticut within 60 miles of Columbus Circle, New York, N.Y. William D. Traub, 10 East 40th Street, New York, N.Y., representative for transferee.

No. MC–FC 66944. By order of June 12, 1964, the Transfer Board approved the transfer to Donald H. Edwardson, doing business as Diffley Truck Line, Topeka, Kans., of the operating rights in Certificate in No. MC 59227, issued February 11, 1960, to N. J. Mabon, doing business as Diffley Truck Line, Topeka, Kans., authorizing the transportation, of regular routes, of: General commodities, excluding household goods, commodities in bulk, and other specified commodities, between Topeka, and Manhattan, Kans., serving all intermediate points, and the off-route point of Louisville, Kans. J. M. Caplinger, 917 Topeka Avenue, Topeka, Kans., attorney for applicants.

[SEAL] HAROLD D. McCOY,
Secretary.

[F.R. Doc. 64–6071; Filed, June 18, 1964; 8:47 a.m.]

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PART II

FEDERAL REGISTER

VOLUME 29 NUMBER 120

Washington, Friday, June 19, 1964

Department of Health, Education, and Welfare

Food and Drug Administration

Drugs; Tests and Methods of Assay and Certification

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER C—DRUGS

PART 147—ANTIBIOTICS INTENDED FOR USE IN THE LABORATORY DIAGNOSIS OF DISEASE

PART 148e—ERYTHROMYCIN

PART 148k—NYSTATIN

PART 148p—POLYMYXIN

PART 148r—TYROTHRICIN

PART 148t—VIOMYCIN

Tests and Methods of Assay and Certification of Antibiotic Drugs Subject to Drug Amendments of 1962

The Commissioner of Food and Drugs has evaluated the views and comments received in response to the notice of proposed rulemaking published in the FEDERAL REGISTER of April 18, 1963 (28 F.R. 3822), and has concluded that the following regulations should issue for the certification of certain antibiotic drugs subject to the Drug Amendments of 1962 (76 Stat. 785–787; Public Law 87–781). Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), Title 21 is amended as hereinafter set forth.

§ 147.1 [Amended]

1. Paragraph (e)(1) of § 147.1 *Antibiotic sensitivity discs; tests and methods of assay; potency* is amended by changing the last sentence to read as follows: "This is the potency obtained for a single assay. Perform two or more replicate assays on each of 2 days. The average of all assays is the potency of the sample disc."

2. Section 147.2 is amended as follows:

By changing the introduction to paragraph (a), by adding thereto the following new subparagraphs, and by changing (c)(1)(iii) to read as set forth below:

§ 147.2 Antibiotic sensitivity discs; certification procedure.

(a) *Standards of identity, strength, quality, and purity.* Antibiotic sensitivity discs are paper or plastic discs or compressed tablets containing antibiotic compounds. If they are tablets they may contain suitable lubricants, binders, and diluents, none of which shall affect the antibacterial spectrums of the antibiotics. Each disc shall have a uniform potency that is equivalent to that contained in a standard disc prepared with one of the following quantities of antibiotic compounds:

* * * * *

(12) Colistin: Not less than 2 μg or not more than 10 μg.

(13) Erythromycin: Not less than 2 μg or not more than 15 μg.

(14) Kanamycin: Not less than 5 μg or not more than 30 μg.

(15) Neomycin: Not less than 5 μg or not more than 30 μg.

(16) Novobiocin: Not less than 5 μg or not more than 30 μg.

(17) Nystatin: 100 units.

(18) Oleandomycin: Not less than 2 μg or not more than 15 μg.

(19) Oxytetracycline: Not less than 5 μg or not more than 30 μg.

(20) Polymyxin B: Not less than 50 units or not more than 300 units.

(21) Ristocetin: Not less than 5 μg or not more than 30 μg.

(22) Vancomycin: Not less than 5 μg or not more than 30 μg.

(23) Viomycin: Not less than 2 μg or not more than 10 μg.

* * * * *

(c) *Labeling.* * * *

(1) * * *

(iii) The statement "Expiration date ----------," the blank being filled in with the date that is 6 months after the month during which the batch was certified, except that the blank may be filled in with a date that is 12, 18, 24, 30, 36, 42, 48, 54, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such longer period of time.

* * * * *

3. Section 147.4 *Antibiotic-dehydrated media-triphenyltetrazolium chloride sensitivity discs* * * * is amended by changing paragraphs (a)(1) and (b) to read:

§ 147.4 Antibiotic-dehydrated media-triphenyltetrazolium chloride sensitivity discs; certification procedure.

(a)(1) Each disc shall contain penicillin G, streptomycin, tetracycline, chloramphenicol, bacitracin, erythromycin, kanamycin, neomycin, novobiocin, oleandomycin, polymyxin B, or ristocetin. If it is tetracycline, it shall contain 5 micrograms.

* * * * *

(b) In all cases, the immediate container shall be sterile at the time of filling and closing. If it is a packaged combination, such package shall contain only those discs described in paragraph (a) of this section.

* * * * *

4. Title 21, Chapter I, is amended by adding thereto the following new sections and parts:

§ 148e.18 Erythromycin ethylsuccinate-butylaminobenzoate intramuscular solution.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate-butylaminobenzoate intramuscular solution is erythromycin ethylsuccinate and butylaminobenzoate dissolved in polyethylene glycol. It contains a suitable and harmless preservative. Each milliliter contains 50 milligrams of erythromycin. It contains 2 percent butylaminobenzoate. It is sterile. It is nontoxic. Its moisture content is not more than 0.5 percent. The erythromycin ethylsuccinate used conforms to the standards prescribed therefor by § 148e.7(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* (i) In addition to the labeling requirements prescribed by § 148.3 of this chapter, each immediate container shall bear on its label and labeling the statement: "Warning—For intramuscular use only."

(ii) Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, moisture, pH, reduce on ignition, identity, and crystallinity.

(*b*) The batch for potency, sterility, toxicity, and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 packages, each containing 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each package or immediate container submitted in accordance with subparagraph (3)(ii) (*a*), (*b*)(*1*), and (*c*) of this paragraph; $10.00 for all immediate containers submitted in accordance with subparagraph (3)(ii) (*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b)(1), except prepare the solution of the sample in the following manner: By means of a syringe, transfer 1 milliliter of the sample to a 100-milliliter volumetric flask, dissolve with 40 milliliters of absolute methyl alcohol, fill to volume and further dilute to the reference point with 0.1*M* potassium phosphate buffer, pH 8.0. The erythromycin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the amount that it is represented to contain.

(2) *Sterility.* Use the entire contents of a single-dose container, or approximately 1 milliliter from each multiple-dose container and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except administer subcutaneously a test dose of 0.1 milliliter of the undiluted solution.

(4) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter, except dissolve the sample with absolute methyl alcohol.

§ 148e.23 Erythromycin ethyl carbonate for pediatric drops.

(a) *Requirements for certification—*(1) *Standards of identity, strength, qual-*

ity, and purity. Erythromycin ethyl carbonate for pediatric drops is a dry mixture of erythromycin ethyl carbonate, suitable and harmless dispersing agents, buffer substances, diluents, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains 100 milligrams of erythromycin. Its moisture content is not more than 2.0 percent. Its pH is not less than 6.5 nor more than 7.0. The erythromycin ethyl carbonate used conforms to the standards prescribed by § 148e.2(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethyl carbonate used in making the batch for potency, toxicity, pH, moisture, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The erythromycin ethyl carbonate used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each immediate container or package submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.11 (b)(1). The erythromycin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter, using 500 milligrams.

(3) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using the suspension reconstituted as directed in the labeling.

PART 148k—NYSTATIN

Sec.

AUTHORITY: The provisions of this Part 148k issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C. 357.

§ 148k.1 Nystatin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin is the yellow to light-tan compound of a kind of nystatin or a mixture of two or more such compounds. It is very slightly soluble in water, moderately soluble in methyl alcohol, butyl alcohol, or propyl alcohol. It is so purified and dried that:

(i) Its potency is not less than 2,000 units of nystatin per milligram.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 5.0 percent.

(iv) Its pH in a 3 percent aqueous suspension is not less than 6.5 and not more than 8.0.

(v) It exhibits absorption maxima within ±2 millimicrons at 230 millimicrons, 291 millimicrons, 305 millimicrons, and 319 millimicrons when dissolved in methyl alcohol, and the ratio of the absorption peak at 230 millimicrons ±2 millimicrons and the middle of the shoulder at 279 millimicrons ±2 millimicrons, $\frac{A_{230}}{A_{279}}$, is not less than 0.90 and not more than 1.25.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, and identity.

(ii) Samples required on the batch: 10 packages, each containing approximately 300 milligrams.

(4) *Fees.* $4.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods:

(i) *Plate assay*—(*a*) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(*b*) *Culture media.* Use ingredients that conform to the standards, if any, prescribed by the U.S.P. or N.F.

(*1*) Make nutrient agar for carrying the organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(2) Make nutrient agar for preparing the inoculated agar plates, as follows:

Peptone	9.4 gm.
Yeast extract	4.7 gm.
Beef extract	2.4 gm.
Sodium chloride	10.0 gm.
Dextrose	10.0 gm.
Agar	23.5 gm.
Distilled water, q.s	1,000.0 ml.

pH 6.0 to 6.2 after sterilization.

In lieu of preparing the media from the individual ingredients as specified, they may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the specified individual ingredients are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(*c*) *Working standard.* Dry an appropriate amount of the working standard for 2 hours at 40° C. at a pressure of 5 millimeters or less. Determine the dry weight and dissolve in sufficient dimethyl formamide to give a stock solution of convenient concentration (usually 1,000 units to 5,000 units per milliliter). This stock solution should be prepared simultaneously with the samples to be tested and should be used for 1 day only.

(*d*) *Preparation of sample.* Dissolve the sample to be tested in sufficient dimethylformamide to give a nystatin concentration of 400 units per milliliter (estimated). Further dilute with 10 percent potassium phosphate buffer, pH 6.0, to 20 units per milliliter (estimated).

(*e*) *Preparation of test organism.* The test organism is Saccharomyces cerevisiae (ATCC 2601, no vitamin requirement), which is maintained on slants of agar described in (*b*)(*1*) of this subdivision. Wash the organism from the agar slant with 3 milliliters of sterile distilled water onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in (*b*)(*1*) of this subdivision. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 37° C. and then wash the resulting growth from the agar surface with about 30 milliliters of sterile distilled water. Standardize the suspension so that a 1:30 dilution of it will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run test plates to determine the quantity of the adjusted stock suspension (not the 1:30 dilution) that should be added (usually 0.7 milliliter) to each 100 milliliters of agar to give clear, sharp inhibition zones of appropriate size.

(*f*) *Preparation of plates.* Melt a sufficient amount of the agar described in (*b*)(2) of this subdivision, cool to 48° C., add the proper amount of the test organism as described in (*e*) of this subdivision, and mix thoroughly. Add 8 milliliters of this inoculated agar to each Petri dish (100 millimeters x 20 millimeters, with flat bottom). Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(*g*) *Standard curve.* Dilute aliquots of the standard stock solution with dimethylformamide to give concentrations of 256, 320, 400, 500, and 624 units of nystatin per milliliter. Dilute these solutions with 10 percent potassium phosphate buffer, pH 6.0, to make concentrations of 12.8, 16.0, 20.0, 25.0, and 31.2 units

per milliliter, respectively. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution, except the 20 units per milliliter, solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with the 20 units per milliliter standard and the other three cylinders with the concentration of the standard concentration under test. Thus, there will be 36 twenty-unit determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 16 hours to 18 hours at 30° C. and measure the diameter of each zone of inhibition. Average the readings of the 20 units per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 36 readings of the 20 units per milliliter concentration. The average of the 36 readings of the 20 units per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 20 units per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 16 units per milliliter concentration, the average of the 36 readings of the 20 units per milliliter concentration is 16.0 millimeters and the average of the 20 units per milliliter concentration of this set of three plates is 15.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 16 units per milliliter concentration of those same three plates is 15.0 millimeters, the corrected value is then 15.2 millimeters. Plot these corrected values, including the average of the 20 units per milliliter concentration, on two-cycle semilog paper, using the concentration in units per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated zone diameter for the lowest concentration of the standard curve;

H = Calculated zone diameter for the highest concentration of the standard curve;

c = Average zone diameter of 36 readings of the 20 units per milliliter standard;

a, b, d, e = Corrected average values for the 12.8, 16.0, 25.0, and 31.2 units per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(*h*) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the 20 units per milliliter standard and three cylinders with the 20 units per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 hours to 18 hours at 30° C. and then measure the diameter of each zone of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 20 units per milliliter zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 20 units per milliliter value on the curve. From the curves, read the potencies corresponding to these corrected values of zone sizes.

(ii) *Turbidimetric assay*—(*a*) *Culture medium.* Make nutrient broth for preparing an inoculum of the test organism as follows:

Peptone	10 gm.
Dextrose	20 gm.
Distilled water, q.s.	1,000 ml.

pH 5.6 to 5.7 after sterilization.

In lieu of preparing the medium from the individual ingredients specified in this subdivision, it may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the individual ingredients specified in this subdivision are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(*b*) *Working standard and standard solutions.* Prepare the standard stock solution as directed in subdivision (i) (*c*) of this subparagraph. Make dilutions of the stock solution with dimethylformamide to obtain concentrations of 121, 139, 184, and 212 units per milliliter. These solutions are then diluted 1:10 with sterile distilled water to obtain concentrations of 12.1, 13.9, 16.0, 18.4, and 21.2 units per milliliter. Add 1.0 milliliter of each such concentration to each of six sterile 20 millimeters x 150 millimeters test tubes. Maintain the sterility of the tubes.

(*c*) *Preparation of sample.* Dissolve the sample to be tested in sufficient dimethylformamide to give a stock solution of convenient concentration. Dilute the stock solution with dimethylformamide to obtain a concentration of 160 units per milliliter (estimated). Further dilute this solution 1:10 with sterile distilled water to obtain a concentration of 16 units per milliliter (estimated). Add 1.0 milliliter of this dilution to each of six sterile 20 millimeters x 150 millimeters test tubes.

(*d*) *Preparation of test organism.* Maintain the test organism Saccharomyces cerevisiae (ATCC 9763) on agar slants as described in subdivision (i) (*e*) of this subparagraph. For use in the assay, prepare an organism suspension by inoculating 100 milliliters of the medium described in (*a*) of this subdivision with a loopful of growth from an agar slant, and incubate the broth culture overnight at 37° C. Adjust this stock suspension, so that a 1:30 dilution in the nutrient broth will give 25 percent light transmission at a wavelength of 580 millimicrons, using a suitable photoelectric colorimeter and a 13-millimeter diameter test tube as an absorption cell. Prepare the inoculum broth by adding from 3 milliliters to 5 milliliters of that adjusted suspension (not the 1:30 dilution) to each liter of nutrient broth needed for the test.

(*e*) *Procedure.* To each of the 20 millimeters x 150 millimeters test tubes prepared in (*b*) and (*c*) of this subdivision, add 9.0 milliliters of the inoculated nutrient broth described in (*d*) of this subdivision, and incubate at 26° C. for 16 hours to 18 hours. After incubation, add 0.5 milliliter of a 12 percent formaldehyde solution to each tube and read the absorbance values in a suitable photoelectric colorimeter, using a wavelength of 530 millimicrons. Set the instrument at zero absorbance with clear, uninoculated broth prepared as described in (*a*) of this subdivision.

(*f*) *Estimation of potency.* Plot the average values for each concentration of the standard on semilog graph paper with absorbance values on the arithmetic scale and nystatin concentrations on the logarithmic scale. Construct the best straight line through the points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated absorbance value for the lowest concentration of the standard curve;

H = Calculated absorbance value for the highest concentration of the standard curve;

a, b, c, d, e = Average absorbance values for each concentration of the standard curve.

Plot the values obtained for L and H and connect the points with a straight line. Average the absorbance values for the sample and read the nystatin concentration from the standard curve. Multiply the concentration by appropriate dilution factors to obtain the nystatin content of the sample.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except inject intraperitoneally each of 5 mice with 0.5 milliliter of a suspension of the drug containing 1,200 units per milliliter in a 0.5 percent acacia solution.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a 3 percent aqueous suspension of the drug.

(5) *Identity.* Weigh approximately 20 milligrams of the sample in a 100-milliliter glass-stoppered volumetric flask, add about 75 milliliters absolute methyl alcohol and shake mechanically for 30 minutes. Dilute to volume with methyl alcohol. Transfer 10.0 milliliters of this solution to a 100-milliliter volumetric flask and dilute to volume with methyl alcohol. Within 2 hours, determine the absorption peak at 230 millimicrons, 291 millimicrons, 305 millimicrons, and 319 millimicrons, and the shoulder at 279±2 millimicrons, using a suitable ultraviolet spectrophotometer and quartz cells. Set the instrument to 100 percent transmission with absolute methyl alcohol. If a recording spectrophotometer is used, record the ultraviolet absorption spectrum from 220 millimicrons to 320 millimicrons. If a non-

recording spectrophotometer is used, the exact positions of the peaks and shoulder should be determined for the particular instrument used. The ratio of the two $\left(\text{absorbances } \frac{A_{230}}{A_{279}}\right)$ should be not less than 0.90 and not more than 1.25.

§ 148k.2 Nystatin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin ointment is composed of nystatin and a suitable and harmless ointment base. Each gram contains 100,000 units of nystatin. The moisture content is not more than 0.5 percent. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 containers, each consisting of 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, one package of each other ingredient used containing 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Using sufficient dimethylformamide to give an estimated concentration of 400 nystatin units per milliliter, blend an accurately weighed representative portion (usually 1 gram) in a high-speed glass blender for 3 minutes. Further dilute with 10 percent potassium phosphate buffer, pH 6.0, to 20 units of nystatin per milliliter, and proceed as directed in § 148k.1(b)(1). Its nystatin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of nystatin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148k.3 Nystatin-neomycin sulfate-gramicidin-triamcinolone acetonide ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin-neomycin sulfate-gramicidintriamcinolone acetonide ointment is nystatin, neomycin sulfate, gramicidin, and triamcinolone acetonide, in a suitable and harmless ointment base. Each gram contains 100,000 units of nystatin, 2.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 1 milligram of triamcinolone acetonide. Its moisture content is not more than 0.5 percent. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (v), (vi), and (vii) of this chapter. The gramicidin used conforms to the standards prescribed by § 148f.1(a)(1) (i), (iii), (iv), (v), and (vi) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*c*) The gramicidin used in making the batch for potency, moisture, residue on ignition, melting point, and identity.

(*d*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of 300 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(*c*) The gramicidin used in making the batch: 10 packages, each consisting of 500 milligrams.

(*d*) The batch: A minimum of 7 immediate containers.

(*e*) In case of an initial request for certification, each other ingredient used: One package of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), (*c*), and (*e*) of this paragraph; $6.00 for each container submitted in accordance with subparagraph (3)(ii)(*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Nystatin content.* Proceed as directed in § 148k.2(b)(1). Its nystatin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin per gram that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 148i.3(b)(1) of this chapter. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin per gram that it is represented to contain.

(iii) *Gramicidin content.* Proceed as directed in § 148f.1(b)(1) of this chapter, except prepare the sample in the following manner: Accurately weigh and dissolve approximately 2 grams of the sample in 50 milliliters of petroleum ether in a separatory funnel. Extract with 20 milliliters of 80 percent ethyl alcohol. Repeat the extraction three times. Pool the extractives and bring to a volume of 100 milliliters with 80 percent ethyl alcohol. Its gramicidin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of gramicidin per gram that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148k.4 Nystatin topical powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin topical powder is a dry powder composed of nystatin and talc. Each gram contains 100,000 units of nystatin. Its moisture content is not more than 2.0 percent. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each containing 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used: One container of each consisting of not less than 5 grams.

(4) Fees. $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Blend the entire contents of an accurately weighed representative sample for 2 to 3 minutes in a high-speed, glass blender with 500 milliliters of dimethylformamide. Dilute with sufficient dimethylformamide to yield a stock solution containing 400 units of nystatin per milliliter. Further dilute in 10 percent potassium phosphate buffer, pH 6.0, and proceed as directed in § 148k.1(b)(1). The potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of nystatin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148k.5 Nystatin-neomycin sulfate-gramicidin topical powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin-neomycin sulfate-gramicidin topical powder is a dry powder composed of nystatin, neomycin sulfate, gramicidin, and talc. Each gram contains 100,000 units of nystatin, 2.5 milligrams of neomycin, and

0.25 milligram of gramicidin. Its moisture content is not more than 2.0 percent. The nystatin used conforms to the standards prescribed by § 418k.1(a)(1) (i), (iii), (iv), and (v). The neomycin sulfate used conforms to the standards prescribed by §148i.1(a)(1) (i), (v), (vi), and (vii) of this chapter. The gramicidin used conforms to the standards prescribed by § 148f.1(a)(1) (i), (iii), (iv), (v), and (vi) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, PH, and identity.

(*c*) The gramicidin used in making the batch for potency, moisture, residue on ignition, melting point, and identity.

(*d*) The batch for nystatin content, neomycin content, gramicidin content, and moisture.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of 300 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(*c*) The gramicidin used in making the batch: 10 packages, each consisting of 500 milligrams.

(*d*) The batch: A minimum of 7 immediate containers.

(*e*) In case of an initial request for certification, each other ingredient used: One package of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), (*c*), and (*e*) of this paragraph; $6.00 for each container submitted in accordance with subparagraph (3)(ii)(*d*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Nystatin content.* Proceed as directed in § 148k.4(b)(1). The nystatin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin per gram that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 148i.1(b)(1) of this chapter, except prepare the sample in the following manner: Blend an accurately weighed representative sample in 500 milliliters of 0.1*M* postassium phosphate buffer, pH 8.0. Further dilute an aliquot to the reference concentration with 0.1*M* potassium phosphate buffer, pH 8.0. The neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of nystatin per gram that it is represented to contain.

(iii) *Gramicidin content.* Proceed as directed in § 148f.1(b)(1) of this chapter, except prepare the sample in the following manner: Dissolve the entire contents or a 1-gram sample in 95 percent ethyl alcohol, and filter. Collect the filtrate, and dilute a portion to the reference concentration with 95 percent ethyl alcohol. The gramicidin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148k.6 Nystatin for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin for oral suspension is a dry powder consisting of nystatin, and suitable and harmless suspending substances, preservatives, diluents, colorings, and flavorings. When the suspension is prepared as directed in its labeling each milliliter contains 100,000 units of nystatin. The pH of the reconstituted drug is not less than 4.9 and not more than 5.5. Its moisture content is not more than 7.0 percent. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency, moisture and pH.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used: One container of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Reconstitute the drug as directed in the labeling. Blend an appropriate aliquot (usually from 1 milliliter to 5 milliliters) in a high-speed, glass blender for 2 to 3 minutes, using 200 milliliters of dimethylformamide. Dilute an aliquot with sufficient dimethylformamide to give a stock solution containing 400 units of nystatin per milliliter. Proceed as directed in § 148k.1(b)(1). Its potency is satisfactory if it contains not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain.

(2) *Moisture.* Using the dry powder, proceed as directed in § 141a.26(e) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the suspension after reconstituting as directed in the labeling.

§ 148k.7 Nystatin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin tablets are tablets composed of nystatin and suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains 500,000 units of nystatin. The moisture content is not more than 5 percent. The tablets shall distintegrate within 2 hours. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used: One container of each consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph; $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Blend a representative number of tablets for 2 to 3 minutes in a high-speed glass blender with 500 milliliters of dimethylformamide. Dilute an aliquot with sufficient dimethylformamide to give a stock solution containing 400 units of nystatin per milliliter. Further dilute an aliquot in 10 percent potassium phosphate buffer, pH 6.0, and proceed as directed in § 148k.1(b)(1). The potency is satisfactory if it contains not less than 90 percent and not more than 130 percent of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148k.8 Nystatin cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, qual-*

ity, and purity. Nystatin cream is composed of nystatin and suitable and harmless emulsifiers, perfumes, buffers, preservatives, and a protectant, in a suitable and harmless cream base. Each gram contains 100,000 units of nystatin. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for potency.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 containers, each consisting of 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay; potency.* Using sufficient dimethylformamide to give an estimated concentration of 400 units of nystatin per milliliter, blend an accurately weighed representative portion (usually 1 gram) in a high-speed blender for 3 minutes. Further dilute with 10 percent potassium phosphate buffer, pH 6.0 to an estimated concentration of 20 units of nystatin per milliliter, and proceed as directed in § 148k.1(b)(1). Its nystatin content is satisfactory if it is not less than 90 percent nor more than 130 percent of the number of units of nystatin that it is represented to contain.

§ 148k.9 Nystatin-neomycin sulfate-gramicidin-triamcinolone acetonide cream.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Nystatin-neomycin sulfate-gramicidin-triamcinolone acetonide cream is composed of nystatin, neomycin sulfate, gramicidin, triamcinolone acetonide, and suitable and harmless emulsifiers, solvents, perfumes, buffers, preservatives, and a protectant, in a suitable cream base. Each gram contains 100,000 units of nystatin, 2.5 milligrams of neomycin, 0.25 milligram of gramicidin, and 1 milligram of triamcinolone acetonide. The nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (v), (vi), and (vii) of this chapter. The gramicidin used conforms to the standards prescribed by § 148f.1(a)(1) (i), (iii), (iv), (v), and (vi) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* (i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*c*) The gramicidin used in making the batch for potency, moisture, residue on ignition, melting point, and identity.

(*d*) The batch for nystatin content, neomycin content, and gramicidin content.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of 300 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(*c*) The gramicidin used in making the batch: 10 packages, each consisting of 500 milligrams.

(*d*) The batch: A minimum of 7 immediate containers.

(*e*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), (*c*), and (*d*) of this paragraph; $6.00 for each package submitted in accordance with subparagraph (3)(ii)(*e*) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Nystatin content.* Proceed as directed in § 148k.2(b)(1). The nystatin content is satisfactory if it is not less than 90 percent nor more than 140 percent of the number of units of nystatin that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 148i.3(b)(1) of this chapter. The neomycin content is satisfactory if it is not less than 90 percent nor more than 140 percent of the number of milligrams of neomycin that it is represented to contain.

(iii) *Gramicidin.* Proceed as directed in § 148f.1(b)(1) of this chapter, except prepare the sample in the following manner: Using 499 milliliters of 95 percent ethyl alcohol and 1 milliliter of polysorbate 80, blend an accurately weighed representative portion, usually 2 grams, in a high-speed glass blender. Further dilute with 95 percent ethyl alcohol to the reference concentration. The gramicidin content is satisfactory if it is not less than 90 percent nor more than 140 percent of the number of milligrams of gramicidin that it is represented to contain.

§ 148k.10 Nystatin-neomycin sulfate-polymyxin B sulfate-fludrocortisone acetate for otic solution.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Nystatin-neomycin sulfate-polymyxin B sulfate-fludrocortisone acetate for otic solution is a dry mixture of nystatin, neomycin sulfate, polymyxin B sulfate, and fludrocortisone acetate. Its moisture content is not more than 6.5 percent. It may be packaged in combination with an immediate container of a suitable and harmless aqueous diluent, containing suitable preservatives and buffers. When reconstituted as directed in the labeling, each milliliter contains 100,000 units of nystatin, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and 1 milligram of fludrocortisone acetate. Its pH is not less than 4.0 and not more than 6.0. They nystatin used conforms to the standards prescribed by § 148k.1(a)(1) (i), (iii), (iv), and (v). The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (v), (vi), and (vii) of this chapter. The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*c*) The polymyxin B sulfate used in making the batch for potency, moisture, residue on ignition, pH, and identity.

(*d*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*c*) The polymyxin B sulfate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*d*) The batch: A minimum of 7 immediate containers.

(*e*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each consisting of 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), (*c*), and (*e*) of this paragraph; $6.00 for each container submitted in accordance with subparagraph (3)(ii)(*d*) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Nystatin.* Proceed as directed in § 148k.6(b)(1). Its nystatin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 148i.1(b)(1) of this chapter, using the suspension obtained after

reconstituting as directed in the labeling. The neomycin content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of neomycin that it is represented to contain.

(iii) *Polymyxin B content.* Use the suspension obtained after reconstituting as directed in the labeling. Proceed as directed in § 148p.1(b)(1) of this chapter, except add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. The polymyxin B content is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter, using the dry powder.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the drug reconstituted as directed in its labeling.

§ 148k.11 Nystatin vaginal tablets.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Nystatin vaginal tablets are tablets composed of nystatin and suitable and harmless diluents, binders, and lubricants. Each tablet contains 100,000 units of nystatin. The moisture content is not more than 5 percent. The disintegration time is not more than 1 hour. The nystatin used conforms to the standards prescribed therefor by § 148k.1(a)(1) (i), (iii), (iv), and (v). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for nystatin content, moisture,, and disintegration time.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 immediate containers of approximately 300 milligrams each.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: 6 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each consisting of 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(2) of this paragraph; $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 148k.-7(b)(1). The nystatin content is satisfactory if it is not less than 90 percent nor more than 130 percent of the number of units of nystatin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter, using distilled water as the immersion fluid.

PART 148p—POLYMYXIN

Sec.

148p.1 Polymyxin B sulfate.
148p.2 Polymyxin B sulfate tablets.
148p.3 Polymyxin B sulfate ointment.
148p.4 Polymyxin B sulfate otic solution.
148p.5 [Reserved]
148p.6 Polymyxin B sulfate soluble tablets.

AUTHORITY: The provision of this Part 148p issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148p.1 Polymyxin B sulfate.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate is the sulfate salt of a kind of polymyxin or a mixture of two or more such salts. It is a white to buff-colored powder. It is so purified and dried that:

(i) Its potency is not less than 6,000 units of polymyxin B per milligram, on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It is nontoxic.

(v) Its moisture content is not more than 7.0 percent.

(vi) Its pH in an aqueous solution containing 5 milligrams per milliliter is not less than 5.0 and not more than 7.5.

(vii) Its residue on ignition is not more than 5 percent.

(viii) If it is intended for systemic medication, its heavy metals content is not more than 100 parts per million.

(ix) It gives positive color identity tests for polymyxin.

(2) *Packaging.* In addition to the requirements of § 148.2 of this chapter, if it is packaged for dispensing and it is intended for intrathecal, intramuscular, or topical use, each immediate container shall contain 500,000 units.

(3) *Labeling.* In addition to the requirements of § 148.3 of this chapter, if the drug is packaged for dispensing its labeling shall bear the statement, "Caution this drug should be given intramuscularly and/or intrathecally only to hospitalized patients so as to provide constant supervision by a physician."

(4) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, toxicity, moisture, pH, residue on ignition, heavy metals, and identity.

(ii) Samples required:

(*a*) If the batch is packaged for repacking or for use as an ingredient in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*2*) For sterility testing: 10 packages, each containing approximately 300 milligrams.

(*b*) If the drug is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers plus one additional package containing 1 gram of the batch.

(*2*) For sterility testing: 10 immediate containers.

(5) *Fees.* $5.00 for each package or immediate container submitted in accordance with subparagraph (4)(ii) (*a*) (*1*) and (*b*)(*1*) of this paragraph; $10.00 for all packages or immediate containers submitted in accordance with subparagraph (4)(ii) (*a*)(2) and (*b*)(2) of this paragraph.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(ii) *Culture media.* Using ingredients that conform to the standards, if any, prescribed by the U.S.P. or N.F., make nutrient agar for carrying the test organism and for the seed and base layers:

(*a*) For carrying the test organism:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Beef extract	1.5 gm.
Yeast extract	3.0 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(*b*) Base layer:

Pancreatic digest of casein	17.0 gm.
Papaic digest of soybean	3.0 gm.
Sodium chloride	5.0 gm.
Dipotassium phosphate	2.5 gm.
Dextrose	2.5 gm.
Agar	20.0 gm.
Distilled water, q.s.	1,000.0 ml.

Final pH 7.3 after sterilization.

(*c*) Seed layer: For the seed layer, make the following changes in the medium described in (*b*) of this subdivision.

Agar	12.0 gm.
Polysorbate 80 (added after boiling)	10.0 gm.

Final pH 7.3 after sterilization.

In lieu of preparing the median from the individual ingredients as specified, they may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such median. Minor modifications of the specified individual ingredients are permissible if the resulting median possesses growth-promoting properties at least equal to the median described.

(iii) *Working standard.* Dry approximately 30 milligrams of the standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine accurately the dry weight, dissolve in 2.0 milliliters of distilled water, and then add sufficient 10 percent potassium phosphate buffer, pH 6.0, to make a 1,000 units per milliliter stock solution. This

solution may be used for 2 weeks if kept in refrigerator.

(iv) *Preparation of sample.* Dissolve an accurately weighed sample in 2 milliliters of distilled water and dilute with sufficient 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration; and, if it is packaged for dispensing, reconstitute as directed in the labeling, remove an accurately measured representative portion with a suitable syringe fitted with a 22-gage needle, and appropriately dilute in 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Further dilute in 10 percent potassium phosphate buffer, pH 6.0, to give a final estimated concentration of 10 units per milliliter of polymyxin.

(v) *Preparation of test organism.* The test organism is Bordetella bronchiseptica (ATCC 4617), which is maintained on slants of agar described in subdivision (ii) (*a*) of this subparagraph. Wash the organism from the agar slant with 3 milliliters of sterile U.S.P. saline T.S. onto a large surface such as that provided by a Roux bottle containing 300 milliliters of agar described in subdivision (ii) (*a*) of this subparagraph. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 37° C. Wash the resulting growth from the agar surface with 50 milliliters of sterile U.S.P. saline T.S. Standardize the suspension, so that a 1:20 dilution will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run test plates to determine the quantity of the 1:20 diluted suspension (usually 0.3 percent) that should be added to each 100 milliliters of agar to give clear, sharp zones of inhibition of appropriate size.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in subdivision (ii) (*b*) of this subparagraph to each Petri dish (20 millimeters by 100 millimeters). Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow it to harden. Melt a sufficient amount of the agar described in subdivision (ii) (*c*) of this subparagraph, cool to 48° C.–50° C., and the proper amount of test organism as described in subdivision (v) of this subparagraph, and mix thoroughly. Add 4 milliliters of this inoculated agar to each Petri dish. Distribute the agar evenly in the plates, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(vii) *Standard curve.* Prepare the daily standard curve by further diluting the 1,000 units per milliliter working standard stock solution in 10 percent potassium phosphate buffer, pH 6.0, to obtain concentrations of 6.4, 8.0, 10.0, 12.5, and 15.6 units per milliliter. Use three plates for the determination of each point on the curve, except the 10.0 units per milliliter concentration, a total of 12 plates. On each of three plates, fill three cylinders with the 10.0 units per milliliter standard, and the other three cylinders with the concentration under test. Thus, there will be thirty-six 10.0-unit determinations and nine determinations for each of the other points on the curve. After incubation, read the diameters of the circles of inhibition in the plates. Average the readings of the 10.0 units per milliliter and the readings of the points tested for each set of three plates, and average also all 36 readings of the 10.0 units per milliliter concentration. The average of the 36 readings of the 10.0 units per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 10 units per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 8.0 units per milliliter concentration, the average of the 36 readings of the 10-unit concentration is 20.0 millimeters and the average for the 10-unit concentration of this set of three plates is 19.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 8.0-unit concentration of these same three plates is 19.0 millimeters, the corrected value is 19.2 millimeters. Plot these corrected values, including the average of the 10 units per milliliter concentration, on semilog paper, placing the concentration in units per milliliter on the logarithmic scale and the diameter of the zone of inhibition on the arithmetic scale. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated zone diameter for the lowest concentration of the standard curve;

H = Calculated zone diameter of the highest concentration of the standard curve;

c = Average zone diameter of 36 readings of the 10 units per milliliter standard;

a, b, d, e = Corrected values for the 6.4, 8.0, 12.5, and 15.6 units per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(viii) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the 10 units per milliliter standard solution and three cylinders with the 10 units per milliliter (estimated) sample, alternating sample and standard. Incubate all plates, including those containing the standard curve, for 16 hours to 18 hours at 37° C. Measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 10 units per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 10 units per milliliter value on the curve. Read the potencies corresponding to these corrected values of zone size. If packaged for dispensing, its content of polymyxin is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of units of polymyxin that it is represented to contain.

(2) *Sterility.* Proceed as directed in § 141a.2 of this chapter using 50 milligrams from each sample tested, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, except use as a test dose 1.0 milliliter per kilogram of solution containing 20,000 units per milliliter in sterile, pyrogen-free U.S.P. saline T.S.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose of 0.5 milliliter of a solution containing 1,200 units per milliliter in sterile U.S.P. saline T.S.

(5) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, except use a solution containing 5 milligrams per milliliter.

(7) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(8) *Heavy metals content.* Proceed as directed in § 148m.1(b)(9) of this chapter.

(9) *Identity.* (i) To a solution of 2 milligrams of polymyxin sulfate in 5 milliliters of water add 0.5 milliliter of triketohydrindene solution (1:1,000) and 2 drops of pyridine, boil for 1 minute, and cool; a blue color develops.

(ii) To a solution of 2 milligrams of polymyxin sulfate in 5 milliliters of water, add 5 milliliters of sodium hydroxide solution (1:10), mix well, and add, dropwise, 5 drops of a cupric sulfate solution (1:100), mixing after the addition of each drop; a reddish-violet color is produced.

§ 148p.2 Polymyxin B sulfate tablets.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate tablets are tablets that contain polymyxin B sulfate, with one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 500,000 units of polymyxin B. The moisture content is not more than 7.0 percent. They shall disintegrate within 30 minutes. The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (iv), (v), (vi), (vii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The polymyxin B sulfate used in making the batch for potency, toxicity,

moisture, pH, residue on ignition, and identity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: Minimum of 30 tablets.

(2) For disintegration time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(4) *Fees.* $0.75 for each tablet in the sample submitted in accordance with subparagraph (3) (ii) (*b*) (*1*) of this paragraph; $3.00 for all tablets in the sample submitted in accordance with subparagraph (3) (ii) (*b*) (2) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3) (ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148p.1 (b) (1), except prepare the sample by blending a representative number of tablets in a high-speed glass blender with an appropriate amount of 10 percent potassium phosphate buffer, pH 6.0, to prepare a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot in 10 percent potassium phosphate buffer, pH 6.0, to a final estimated concentration of 10 units of polymyxin B per milliliter. The potency is satisfactory if it contains not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148p.3 Polymyxin B sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate ointment is polymyxin B sulfate in a suitable and harmless ointment base. Its potency is 20,000 units per gram. Its moisture content is not more than 1.0 percent. The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a) (1) (i), (v), (vi), (vii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148p.1 (b) (1), except prepare the sample by accurately weighing a representative portion of the ointment (usually 1.0 gram) and transferring it to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake with four 25-milliliter portions of 10 percent potassium phosphate buffer, pH 6.0, and combine the aqueous extractives. After adjusting the volume of the combined extractives to 100 milliliters with 10 percent potassium phosphate buffer, pH 6.0, remove an aliquot and further dilute with 10 percent potassium phosphate buffer, pH 6.0, to obtain a final estimated concentration of 10 units of polymyxin B per milliliter. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of units per gram that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148p.4 Polymyxin B sulfate otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate otic solution is polymyxin B sulfate with or without one or more suitable and harmless preservatives and buffer substances, in a suitable and harmless vehicle. Each milliliter contains 10,000 units of polymyxin B. It may contain 5.0 milligrams of hydrocortisone per milliliter. It is sterile. If it contains acetic acid, its pH is not less than 3.8 and not more than 4.3. The polymyxin B sulfate used conforms to the standards of § 148.1(a) (1) (i), (v), (vi), (vii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The polymyxin B sulfate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, and identity.

(*b*) The batch for potency, sterility, and, if it contains acetic acid, pH.

(ii) Samples required:

(*a*) Polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 5 immediate containers.

(2) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container submitted in accordance with subparagraph (3) (ii) (*a*) and (*b*) (*1*) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (3) (ii) (*b*) (2) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148p.1 (b) (1), except prepare the sample by diluting volumetrically a representative portion (usually 1.0 milliliter) in 10 percent potassium phosphate buffer, pH 6.0, to give a stock solution of convenient concentration. Further dilute an aliquot in 10 percent potassium phosphate buffer, pH 6.0, to give a final estimated concentration of 10 units of polymyxin B per milliliter. Its content of polymyxin B is satisfactory if it contains not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Sterility.* Use 0.25 milliliter from each immediate container and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted solution.

§ 148p.5 [Reserved]

§ 148p.6 Polymyxin B sulfate soluble tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate soluble tablets are tablets composed of polymyxin B sulfate and one or more suitable and harmless binders and fillers. Each tablet contains 250,000 units of polymyxin B. The moisture content is not more than 5.0 percent. The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1 (i), (iv), (v), (vi), (vii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The polymyxin B sulfate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 30 tablets.

(c) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(b) of this paragraph; $4.00 for each package submitted in accordance with subparagraph (3)(ii) (a) and (c) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148p.1(b)(1), except prepare the sample for assay by placing a representative number of tablets into a volumetric flask of appropriate size. Swirl the tablets in a quantity of distilled water just sufficient to dissolve them. Adjust to volume with 10 percent potassium phosphate buffer, pH 6.0. Further dilute an aliquot to a final estimated concentration of 10 units of polymyxin B per milliliter in 10 percent potassium phosphate buffer, pH 6.0. The potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

PART 148r—TYROTHRICIN

§ 148r.1 Tyrothricin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tyrothricin is a white to brownish-white compound of a kind of tyrothricin or a mixture of two or more such compounds. It consists principally of gramicidin and tyrocidine. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,400 micrograms of tyrothricin per milligram.

(ii) Its moisture content is not more than 5 percent.

(iii) It gives a positive identity test for tyrothricin.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, and identity.

(ii) Samples required from each batch: 5 packages, each containing approximately 300 milligrams.

(4) *Fees.* $4.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Tyrothricin is assayed using the gramicidin working standard. Proceed as directed in § 148f.1(b)(1) of this chapter, except dilute the tyrothricin sample to a final estimated concentration of 0.20 microgram of tyrothricin per milliliter. Average the absorbance values for the tyrothricin sample, and read the gramicidin concentration from the gramicidin standard curve. Multiply by 5 to obtain the number of micrograms of tyrothricin in the sample.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Identity.* To 5 milliliters of *p*-dimethylaminobenzaldehyde (T.S.) add about 5 milligrams of tyrothricin, shake well for 2 minutes, then add 2 drops of a 0.1*M* sodium nitrite and 5 milliliters of water. A blue color is produced.

(Sec. 507, 59 Stat. 463, as amended, 76 Stat. 785, 786, 787; 21 U.S.C.A. 357)

PART 148t—VIOMYCIN

§ 148t.1 Viomycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Viomycin sulfate is the sulfate salt of viomycin. It is so purified and dried that:

(i) Its potency is not less than 700 micrograms of viomycin per milligram, on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It is nontoxic.

(v) It contains no histamine nor histamine-like substances.

(vi) Its moisture content is not more than 5 percent.

(vii) Its pH in an aqueous solution containing 100 milligrams per milliliter is not less than 4.5 and not more than 7.0.

(viii) Its absorption maximum at approximately 268 $m\mu$ does not vary more than ±3 millimicrons from that of the viomycin working standard, similarly treated.

(2) *Packaging.* In addition to the requirements of § 148.2 of this chapter, if it is packaged for dispensing the viomycin content shall be 1 gram or 5 grams of viomycin per immediate container.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(4) *Request for certification; sample.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, toxicity, histamine, moisture, pH, and identity.

(ii) Samples required:

(a) If the batch is packaged for repacking or for use in the manufacture of another drug:

(1) For all tests except sterility: A minimum of 10 packages, each containing 300 milligrams.

(2) For sterility: 10 packages, each containing 300 milligrams.

(b) If the batch is packaged for dispensing:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility: 10 immediate containers.

(5) *Fees.* $5.00 for each container in the sample submitted in accordance with subparagraph (4)(ii) (a)(1) or (b)(1) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (4)(ii) (a)(2) or (b)(2) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods:

(i) *Plate assay*—(a) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(b) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(1) Make nutrient agar for carrying the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(2) Make nutrient agar for preparing the inoculated plates as follows:

Beef extract	1.5 gm.
Yeast extract	3.0 gm.
Peptone	6.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in (b) of this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the individual ingredients specified in (b) of this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(c) *Working standard.* Dry approximately 30 milligrams of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight, and dissolve in sufficient distilled water to obtain a stock standard solution of 1,000 micrograms per milliliter. Keep this stock solution in a refrigerator. Do not use it later than 1 week after it is made.

(d) *Preparation of sample.* Dissolve the sample to be tested in 0.1*M* potassium phosphate buffer, pH 8.0, to give a concentration of 50 micrograms of viomycin per milliliter (estimated).

(e) *Preparation of test organism.* The test organism is Bacillus subtilis (ATCC 6633). Maintain the test organism on nutrient agar prepared as described in (b)(1) of this subdivision. Prepare a spore suspension by one of the following methods:

(1) Grow the organism for 1 week at 37° C. in a number of Roux bottles, each containing 300 milliliters of nutrient agar prepared as described in (b)(1) of this subdivision. Suspend the spores in sterile distilled water, and heat for 30 minutes at 70° C. Wash the spore suspension three times with sterile distilled water, heat again for 30 minutes at 70° C., and resuspend in sterile distilled water; or

(2) Grow the organism for 5 days at 37° C. in a Roux bottle containing 300 milliliters of the agar medium described in (b)(1) of this subdivision, but modified by the addition of 300 milligrams of $MnSO_4 \cdot H_2O$ per liter. Suspend the growth in 50 milliliters of sterile U.S.P. saline T.S., centrifuge, and decant the

supernatant liquid. Reconstitute the sediment and heat-shock the suspension by heating for 30 minutes at 70° C. Maintain the spore suspension at approximately 15° C. Determine by appropriate tests the quantity of spore suspension to be added to each 100 milliliters of agar for the secondary layer that will give sharp, clear zones of inhibition.

(*f*) *Preparation of plates.* Add 10 milliliters of melted agar prepared as described in (*b*) (2) of this subdivision to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates, cover with porcelain covers glazed only on the outside, and allow to harden. Use the plates the same day they are prepared. Melt the agar to be used for the second layer, cool to 55° C. to 60° C., and add the spore suspension prepared as described in (*e*) of this subdivision. Mix thoroughly, and add 4 milliliters to each of the plates containing the 10 milliliters of uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(*g*) *Standard curve.* Prepare the daily standard curve by further diluting the 1,000 micrograms per milliliter stock solution in 0.1*M* potassium phosphate buffer (pH 8.0) to obtain concentrations of 32.0, 40.0, 50.0, 62.5, and 78.1 micrograms per milliliter. Use three plates for the determination of each point on the curve, except the 50.0 micrograms per milliliter concentration, a total of 12 plates. On each of three plates fill three cylinders with the 50.0 micrograms per milliliter standard, and the other three cylinders with the concentration under test. Thus, there will be thirty-six 50-microgram determinations and nine determinations for each of the other points on the curve. After incubation, read the diameters of the circles of inhibition in the plates. Average the readings of the 50.0 micrograms per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 36 readings of the 50.0 micrograms per milliliter concentration. The average of the 36 readings of the 50.0 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 50.0 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 40.0 microgram concentration, the average of the 36 readings of the 50.0 microgram concentration were 20.0 millimeters, and the average of the 50.0-microgram concentration of this set of three plates were 19.8 millimeters, the correction would be +0.2 millimeter. If the average reading of the 40.0-microgram concentration of these same three plates were 19.0 millimeters, the corrected value would be 19.2 millimeters. Plot these corrected values, including the average of the 50.0 micrograms per milliliter concentration, on 2-cycle semilog paper, using the concentrations in micrograms per milliliter as the ordinate (logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated zone diameter for the lowest concentration of the standard curve;

H = Calculated zone diameter for the highest concentration of the standard curve;

c = Average zone diameter of 36 readings of the 50.0 micrograms per milliliter standard;

a, b, d, e = Corrected average values for the 32.0, 40.0, 62.5, and 78.1 micrograms per milliliter standard solutions, respectively.

Plot the values obtained for L and H, and connect with a straight line.

(*h*) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the standard 50 micrograms per milliliter solution and three cylinders with the 50.0 micrograms per milliliter (estimated) sample, alternating standard and sample. Incubate all plates, including those containing the standard curve at 37° C. overnight, and measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 50.0 micrograms per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 50.0 micrograms per milliliter value on the curve, and read the potencies corresponding to these corrected values of zone sizes.

(ii) *Turbidimetric assay—(a) Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(*1*) Make nutrient agar for carrying the organism, as follows:

Beef extract	1.5 gm.
Yeast extract	3.0 gm.
Peptone	6.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(*2*) Make nutrient broth for preparing an inoculum of the test organism as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Dextrose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium dihydrogen phosphate	1.32 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredient specified in this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the individual ingredients specified in this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(*b*) *Test culture.* Employ the agar described in (*a*) (*1*) of this subdivision for maintaining the test organism which is Klebsiella pneumoniae (ATCC 10031), noncapsulated. Transfer stock cultures every week for test purposes. Transfer the organism to fresh agar slants and incubate overnight at 37° C. Suspend the growth from two or three of these slants in sterile U.S.P. saline T.S., and add approximately 5 milliliters of culture suspension to each of two Roux bottles containing the agar described in (*a*) (*1*) of this subdivision. Incubate the bottles overnight at 37° C., harvest the growth using 50 milliliters of sterile U.S.P. saline T.S. per bottle, and pool the washings from the two bottles. Determine the dilution with sterile U.S.P. saline T.S. that will give a light transmission reading of 25 percent, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Keep the resulting suspension of organisms in the refrigerator and use for a period not to exceed 2 weeks. Prepare the daily inoculum by adding 0.1 milliliter–0.2 milliliter of the suspension to each 100 milliliters of the nutrient broth prepared as directed in (*a*) (*2*) of this subdivision, cooled to a temperature of approximately 15° C.

(*c*) *Working standard and standard curve.* To prepare solutions for the standard curve, dilute the 1,000 micrograms per milliliter working standard described in (i) (*c*) of this subparagraph in distilled water to make concentrations of 64, 80, 100, 125, and 156 micrograms of viomycin per milliliter. The 100 micrograms per milliliter concentration is the reference point of the curve. Add 1.0 milliliter of each dilution to each of three test tubes (16 millimeters x 125 millimeters).

(*d*) *Preparation of sample.* Dilute the sample under test in sterile distilled water to contain 100 micrograms per milliliter (estimated). Add 1.0 milliliter of this dilution to each of three test tubes (16 millimeters x 125 millimeters).

(*e*) *Procedure.* To each of the tubes prepared as described in (*c*) and (*d*) of this subdivision, add 9.0 milliliters of the inoculated broth prepared as outlined in (*b*) of this subdivision. Place all tubes immediately in a water bath at 37° C. for 3 hours to 4 hours. After incubation, add 0.5 milliliter of 12 percent formaldehyde to each tube. Read the absorbance values of each tube in a suitable photoelectric colorimeter, using a wavelength of 530 millimicrons. Set the instrument to zero absorbance with clear, uninoculated broth.

(*f*) *Estimation of potency.* Plot the average absorbance values for each concentration of the standard on two-cycle semilogarithmic graph paper with absorbance values on the arithmetic scale and concentrations on the logarithmic scale. Construct the best straight line through the points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated absorbance value for the lowest concentration of the standard curve;

H=Calculated absorbance value for the highest concentration of the standard curve;

a, b, c, d, e=Average absorbance values for each concentration of the standard curve.

Plot the values obtained for L and H, and connect the points with a straight line. Average the absorbance value for the sample and read the viomycin concentration from the standard curve. Multiply the concentration by appropriate dilution factors to obtain the viomycin content of the sample.

When packaged for dispensing, its potency is satisfactory if it contains not less than 90 percent nor more than 115 percent of the number of milligrams that it is represented to contain.

(2) *Sterility.* Using 300 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Using as a test dose 1.0 milliliter per kilogram of a sterile, pyrogen-free U.S.P. saline test solution containing 10 milligrams of viomycin per milliliter, proceed as directed in § 141a.3 of this chapter.

(4) *Toxicity.* Using as a test dose 0.5 milliliter of a sterile U.S.P. saline test solution, containing 2 milligrams of viomycin per milliliter, proceed as directed in § 141a.4 of this chapter.

(5) *Histamine.* Using as a test dose 0.6 milliliter per kilogram of a sterile U.S.P. saline test solution containing 5 milligrams of viomycin per milliliter, proceed as directed in § 141b.105 of this chapter.

(6) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(7) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using an aqueous solution containing 100 milligrams of viomycin per milliliter.

(8) *Identity*—(i) *Phosphate buffer solution.* Mix 296.3 milliliters of 0.1*N* sodium hydroxide with 500 milliliters of 0.05*M* postassium phosphate (6.805 grams of KH_2PO_4 per 1,000 milliliters of water) and dilute with sufficient water to make 1 liter.

(ii) *Procedure.* Dissolve the working standard and the sample to be tested in sufficient potassium phosphate buffer solution to give solutions containing 10 micrograms per milliliter. Measure the ultraviolet absorption of each solution in a suitable spectrophotometer. Compare the spectrum of the sample qualitatively with that of the standard.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER.

(Sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357)

Dated: June 15, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

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