Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Antiviral Prophylaxis Rpt	100	1	0.25	25
Total				421

Dated: March 15, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–6792 Filed 3–20–96; 8:45 am]

BILLING CODE 4163–18–P

[30DAY–08]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090.

The following request has been submitted for review since the last publication date on February 6, 1996:

Proposed Project

Hanford Environmental Dose Reconstruction (HEDR) Project Milk Producers Survey—New—OMB approved the information collections for the ''Hanford Thyroid Disease Full Epidemiology Study'' under OMB No. 0920–0296 to determine the health effects to the public from radioactive releases from the Hanford Nuclear Site Operations during the 1940's and 1950's. A primary component of these releases was radioactive iodine. Consumption of fresh milk from cows that have eaten contaminated vegetation and fresh leafy vegetables and eggs from chickens with access to outdoor vegetation are important pathways of radioactive iodine to the human body which adversely affects the thyroid gland. To estimate the doses to the thyroid that individuals and populations could have received, historical milk cow and chicken feeding and distribution practices must be reconstructed for the downwind area. This information is particularly important for use in this ongoing study and its relation to radiation exposures. Researchers from LTG Associates will collect information from a representative sample of individuals who farmed in 7 counties within the study area during the periods of 1945 and 1951.

Respondents	No. of respondents	No. of responses/respondents	Avg. burden/response (in hrs.)
Contact Potential Sources of Names of farmers	50	1	0.16
Initial Contact of Potential Candidates	1,600	1	0.16
Scheduling Interview	400	1	0.08
Telephone Interview	400	1	2

The total annual burden is 1108. Send comments to Allison Eydt; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–6793 Filed 3–20–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0084]

Agency Emergency Processing Request Under OMB Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995. The purpose of the proposed collection of information is to enable FDA to compile lists of U.S. processors that export certain animal-derived foods to the European Community (EC). These lists must be completed by May 1, 1996, to meet EC trade requirements. To meet the EC deadline, FDA is requesting OMB approval by March 28, 1996.

DATES: Submit written comments by March 28, 1996.

ADDRESSES: Submit written comments to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the Paperwork Reduction Act of 1995 and 5 CFR 1320.13 because the information is needed to meet the May 1, 1996, EC deadline; the information is essential to the agency's mission; and public harm is reasonably likely to result if normal clearance procedures are followed.

With respect to the following collection of information, comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of the agency s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Information from U.S. Processors that Export Shell Eggs, Dairy Products, Game Meat and Game Meat Products to the European Community:

The EC is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed below, EC legislation requires assurance from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations, FDA intends to request information from processors that export certain animal-derived products (shell eggs, dairy products, game meat and game meat products) to the EC. FDA will use this information to compile lists of processors that meet U.S. requirements and will provide the lists to the EC quarterly. Inclusion on the lists is voluntary. EC member countries will refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the processor list are subject to detention and possible refusal at the port. FDA intends to request the following information from each processor:

(1) Business name and address;

(2) Name and telephone number of person designated as business contact;

(3) Lists of products presently being shipped to the EC and those intended to be shipped in the next 2 years;

(4) Name and address of manufacturing plants for each product and;

(5) Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier, such as plant number; and last date of inspection.

FDA estimates the burden of the proposed collection of information is as follows:

SHELL EGGS

Estimated Annual Reporting Burden				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25	1	25	0.25	6.25

DAIRY PRODUCTS

Estimated Annual Reporting Burden				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
50	1	50	0.25	12.50

GAME MEAT AND GAME MEAT PRODUCTS

Estimated Annual Reporting Burden				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25	1	25	0.25	6.25

There are no capital costs or operating and maintenance costs associated with this collection.

Third Party Disclosure

The following estimate of the burden on trade associations assumes that the trade associations will disseminate FDA's information request through a mass mailing to their membership or publish it in their trade magazine or newsletter:

Estimated Annual Reporting Burden				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12	1	12	8	96

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: March 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–6737 Filed 3–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0022]

Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance manual entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996).'' This guidance manual was developed by FDA's Center for Biologics Evaluation and Research (CBER). The manual provides guidance for the submission of computer assisted license applications. The guidance manual is intended to increase the efficiency and quality of the review process for applicants and FDA. The manual also supersedes a previous Points to Consider guidance made available in November 1990.

DATES: Written comments by June 19, 1996.

ADDRESSES: Submit written requests for single copies of the guidance manual entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996)'' to the Division of Congressional and Public Affairs (HFM–11), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. The guidance manual may also be obtained by mail or FAX by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709.

Additionally, persons with access to the INTERNET may obtain the guidance manual in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:
http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requesters should connect to FDA's FTP Server, FTP.FDA.GOV (192.73.61.21). CBER's documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail''. A message should be sent to: ''CAPLA@a1.cber.fda.gov''.

Submit written comments on the guidance manual to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance manual and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: One of FDA's continuing objectives is to improve the speed and quality of its biologics licensing review and approval program. In order to reach a decision to approve a license application the agency must evaluate all information and data provided by applicants that support the safety, purity, potency, and efficacy of the proposed product. To make the review process more efficient for industry and FDA, CBER is utilizing electronic information systems technology. FDA believes the increased use of CAPLA's and computerization will enhance the timeliness, effectiveness, and efficiency of the biologics review process and reduce burdensome, nonessential hard-copy handling and storage.

In the Federal Register of November 20, 1990 (55 FR 48291), FDA announced the availability of a document entitled ''Points to Consider (PTC): Computer Assisted Submissions for License Applications.'' Since the publication of that document, CBER has gained considerable experience and expertise in the area of electronic information transfer. FDA is announcing in this Federal Register notice a document entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996).'' This new manual supersedes the 1990 PTC document, and should be used as guidance by applicants for electronically submitting license applications or new drug applications (NDA's) to CBER.

A CAPLA is any electronic submission, ranging from a single diskette containing data files to a complete system including custom software and sponsor-owned hardware. Over time, CBER expects CAPLA's will evolve from stand-alone systems to submissions containing just electronic information files, with no applicant provided hardware or software. Applicants should confer with the CBER CAPLA coordinator early in the development of a CAPLA to assess whether it is necessary to include ''commercial off the shelf'' (COTS) software products or custom developed tools to support the CAPLA submission. The manual contains a listings of preferred COTS software and CBER contacts.

The guidance manual provides general information to applicants on the design, development, and submission of CAPLA's. The guidance manual is intended to address the special circumstances to be considered when an applicant electronically submits information in support of a license application; however, the guidance manual does not explain the scientific, clinical, or regulatory aspects of preparing a license application.

The manual is divided into four main sections: (1) Introduction; (2) CAPLA design and development; (3) CAPLA delivery and operations; and (4) CBER's computing environment. The manual also provides information regarding the following topics: Joint planning between the applicant and CBER, cross-platform tools, clinical review, CAPLA guidance for biostatistical review, data presentation formats, communication with CBER, CBER contacts, and license application forms.

The CAPLA guidance manual provides information regarding milestones that the applicant should consider when planning for CAPLA submissions. The following milestones are outlined in the guidance manual: (1) 12 to 18 months before submission: confer on network system requirements; (2) 6 months before submission: confer on CAPLA structure and content; (3) 1 to 3 months before submission: provide demonstration or prototype CAPLA; (4) 30 days before submission: submit