

restrictions on carrier entry or capacity in any market; and

(iv) Whether the country's government is honoring the provisions of the bilateral aviation agreement and there are no significant bilateral problems.

(b) By petition or on the Department's own initiative, new country-pair markets will be listed in the appropriate category, and existing country-pair markets may be transferred between categories.

(c) Air carriers and foreign air carriers are exempted from the duty to file governing rules tariffs containing general conditions of carriage with the Department of Transportation, as required by 49 U.S.C. 41504 and 14 CFR part 221. An initial description of the general conditions of carriage will be included in the Assistant Secretary's notice.

(d) Notwithstanding paragraph (c) of this section, air carriers and foreign air carriers shall file and maintain a tariff with the Department to the extent required by 14 CFR § 203.4 and other implementing regulations.

(f) Authority for determining what rules are covered by paragraph (c) and for determining the filing format for the tariffs required by paragraph (d) is delegated to the Director of the Office of International Aviation.

#### § 293.11 Required statement.

Each governing rules tariff shall include the following statements:

(a) "Rules herein containing general conditions of carriage are not part of the official U.S. D.O.T. tariff."

(b) "The rules and provisions contained herein apply only to the passenger fares and charges that the U.S. Department of Transportation requires to be filed as tariffs."

#### § 293.12 Revocation of exemption.

(a) The Department, upon complaint or upon its own initiative, may, immediately and without hearing, revoke, in whole or in part, the exemption granted by this part with respect to a carrier or carriers, when such action is in the public interest.

(b) Any such action will be taken in a notice issued by the Assistant Secretary for Aviation and International Affairs, and will identify the tariff matter to be filed, and the deadline for carrier compliance.

(c) Revocations under this section will have the effect of reinstating all applicable tariff requirements and procedures specified in the Department's Regulations for the tariff material to be filed, unless otherwise specified by the Department.

### Subpart C—Effect of Exemption

#### § 293.20 Rule of construction.

To the extent that a carrier holds an effective exemption from the duty to file tariffs under this part, it shall not, unless otherwise directed by order of the Department, be subject to tariff posting, notification or subscription requirements set forth in 49 U.S.C. 41504 or 14 CFR part 221, *except* as provided in § 293.21.

#### § 293.21 Incorporation of contract terms by reference.

Carriers holding an effective exemption from the duty to file tariffs under this part may incorporate contract terms by reference (*i.e.*, without stating their full text) into the passenger ticket or other document embodying the contract of carriage for the scheduled transportation of passengers in foreign air transportation, *provided that*:

(a) The notice, inspection, explanation and other requirements set forth in 14 CFR 221.107, paragraphs (a), (b), (c) and (d) are complied with, to the extent applicable;

(b) In addition to other remedies at law, a carrier may not claim the benefit under this section as against a passenger, and a passenger shall not be bound by incorporation of any contract term by reference under this part unless the requirements of paragraph (a) of this section are complied with, to the extent applicable; and

(c) The purpose of this section is to set uniform disclosure requirements, which preempt any conflicting State requirements on the same subject, for incorporation of terms by reference into contracts of carriage for the scheduled transportation of passengers in foreign air transportation.

#### § 293.22 Effectiveness of tariffs on file.

(a) Ninety days after the date of effectiveness of the Assistant Secretary's notice, passenger tariffs on file with the Department covered by the scope of the exemption will cease to be effective as tariffs under 49 U.S.C. 41504 and 41510, and the provisions of 14 CFR part 221, and will be canceled by operation of law.

(b) Ninety days after the date of effectiveness of the Assistant Secretary's notice, pending applications for filing and/or effectiveness of any passenger tariffs covered by the scope of the exemption, will be dismissed by operation of law. No new filings or applications will be permitted after the date of effectiveness of the Assistant Secretary's notice except as provided under § 293.12.

Issued in Washington, DC, on February 27, 1997.

Charles A. Hunnicutt,

*Assistant Secretary for Aviation and International Affairs.*

[FR Doc. 97-5361 Filed 3-7-97; 8:45 am]

BILLING CODE 4910-62-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 163

[Docket Nos. 86P-0297 and 93P-0091]

### White Chocolate; Proposal to Establish a Standard of Identity

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to establish a standard of identity for white chocolate. The proposed standard will provide for the use of the term "white chocolate" as the common or usual name of products made from cacao fat, milk solids, nutritive carbohydrate sweeteners, and other safe and suitable ingredients, but containing no nonfat cacao solids. This action responds principally to citizen petitions submitted separately by the Hershey Foods Corp. (Hershey) and by the Chocolate Manufacturers Association of the United States of America (CMA). FDA tentatively concludes that this action will promote honesty and fair dealing in the interest of consumers and, to the extent practicable, will achieve consistency with existing international standards of identity for white chocolate.

**DATES:** Written comments by May 27, 1997. The agency proposes that any final rule that may be issued based upon this proposal become effective January 1, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of June 5, 1992 (57 FR 23989), FDA published a

tentative final rule (hereinafter referred to as the 1992 tentative final rule) to amend the standards of identity for cacao products in part 163 (21 CFR part 163). In section II.B. of the 1992 tentative final rule, FDA noted that it had received a comment that requested that the agency adopt a standard of identity for white chocolate. In support of that request, the comment argued that the absence of a standard of identity for this food had limited the introduction of "white chocolate" products into the market. The comment also noted the likelihood that consumer confusion would develop about the content of products informally referred to as "white chocolate" that may or may not contain any cacao-derived ingredients.

The comment observed that, in the absence of a standard of identity for this product, the term "white chocolate" would be prohibited under the existing standards of identity in part 163. Further, the comment stated that when such products have been introduced, firms have been forced to use alternative names to avoid the labeling constraints in the standards of identity.

In response to the comment, FDA recognized the dilemma faced by U.S. manufacturers of those confections that may be labeled "white chocolate" in other countries but stated that the adoption of a standard of identity for white chocolate was outside the scope of that rulemaking. The agency suggested that the manufacturer petition the agency to adopt a standard for this food. FDA pointed out that, in fact, in the Federal Register of September 16, 1991 (56 FR 46798), the agency had granted Hershey a temporary marketing permit (TMP) to test market a product called "white chocolate." The permit provided for the temporary market testing of 23,608 kilograms (kg) (52,000 pounds (lb)) of the product for a period of 15 months.

Since publication of the 1992 tentative final rule, the agency has received several applications from chocolate manufacturers for TMP's for "white chocolate." In the Federal Register of November 5, 1993 (58 FR 59050), the agency granted Hershey a new TMP for test products designated as "white chocolate." The purpose of the new permit was to permit Hershey to collect data on consumer acceptance of the product over a wider area of distribution. Hershey said that it intended to use these data to support its citizen petition (filed December 15, 1992, Docket No. 86P-0297/CP2) (hereinafter referred to as the 1992 Hershey petition) for a standard of identity for white chocolate. In the November 5, 1993 notice, the agency

announced that it had received a citizen petition from CMA (filed March 2, 1993, Docket No. 93P-0091) (hereinafter referred to as the 1993 CMA petition) that also requested that FDA establish a standard of identity for white chocolate.

In addition to Hershey, the agency has granted TMP's to Ganong Bros., Ltd., St. Stephen NB, Canada E3L 2X5 (58 FR 59050, November 5, 1993), the Pillsbury Co. (59 FR 32443, June 23, 1994), and Kraft General Foods, Inc. (59 FR 33976, July 1, 1994).

In the Federal Register of December 29, 1994 (59 FR 67302), FDA published a notice extending Hershey's TMP (Docket No. 93P-0310) and inviting interested persons to participate in the extended market test under the same conditions that applied under that TMP. Since January 1995, FDA has issued letters to The Proctor and Gamble Co., Brach and Brock (formerly E. J. Brach Corp.), Mauna Loa Macadamia Nut Corp., Nestlé Food Co., Kraft General Foods, MacFarms of Hawaii, Van Leer Chocolate Corp., and Wilbur Chocolate Co. acknowledging the firms' acceptance of the agency's invitation to participate in the extended market test of products identified as being or containing white chocolate. The aggregate effect of these TMP's is that up to 75 million kg (166 million lb) per annum of product consisting, in large part, of white chocolate has been, or will be, market tested. The majority of the firms are conducting nationwide market tests. The agency is currently evaluating requests from other firms to participate in the extended market test.

## II. Petitions and Grounds

### A. The 1992 Hershey Petition

Hershey, in its 1992 petition requesting that FDA establish a standard of identity for white chocolate, described the product named "white chocolate" as a food that deviates from the standardized cacao products in part 163 in that: (1) It is prepared without the nonfat components of the ground cacao nibs but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) it may contain safe and suitable antioxidants. The petition further described "white chocolate" as the solid or semiplastic food prepared by mixing and grinding cocoa butter with one or more nutritive sweeteners and one or more of the optional dairy ingredients provided in part 163. It contains not less than 20 percent cocoa butter, not less than 14 percent of total milk solids, not less than 3.5 percent milkfat, and not more than 55 percent nutritive carbohydrate sweeteners. It may contain emulsifying agents, spices,

natural and artificial flavorings and other seasonings, and antioxidants approved for food use. It contains no coloring material.

In support of its request, Hershey contended that, because there is currently no standard of identity for white chocolate, virtually all uses of the term "white chocolate" would be prohibited by the existing standards of identity for chocolate because they prescribe the presence of chocolate liquor (ground cacao nibs). Hershey argued that this requirement has acted as a practical deterrent to companies that have considered developing and marketing white chocolate products in the United States. The Hershey petition noted that when such products have been introduced and marketed in the United States, manufacturers have had to resort to labeling such products with descriptive terms other than "white chocolate" (e.g., "white confection") to avoid standardized food labeling issues. Hershey contended that, in many cases, the use of such alternative terminology has obscured the true nature of the product and could potentially mislead consumers. Therefore, Hershey maintained that the absence of a standard of identity for white chocolate, and the resulting uncertainty over nomenclature on labeling, have proven to be factors limiting the introduction of new products to meet consumer demand.

In further support of its petition, Hershey maintained that there exists a good likelihood of consumer confusion with regard to the content of products that are referred to informally as "white chocolate" but that may or may not contain any cacao-derived ingredients. According to Hershey, consumers expecting to purchase a white chocolate product may, in fact, be purchasing a vegetable fat coating-type product made from fats other than cacao fat, which may contain little or no cacao ingredients.

The Hershey petition also included a summary of the results of a consumer survey conducted in 1990 to determine the most common name used by adult candy consumers when shown a variety of confection products, including a white confection bar. The survey was conducted by personal interviews with 216 adults who eat candy regularly. After an introductory statement on how people use different names for the same product, respondents were shown a product and asked what they would call it. The procedure was repeated for two or more products—jelly beans, lollipops, and a white confection bar. Over 61 percent of the respondents used the term "white chocolate" to describe

the white confection bar that they were shown. An additional 10 percent of the respondents associated the bar product to chocolate. Hershey contended that, based on these results, it appears that the majority of candy consumers tend to identify the white confection as either "white chocolate" specifically or as some variety of chocolate.

Hershey pointed out that many countries that have adopted standards for cacao products have also recognized and established a standard of identity for white chocolate. Hershey argued that, in countries that have established a standard of identity for white chocolate, in contrast to the United States, consumers are able to evaluate the quality and value of the white chocolate products they purchase without having to resort to an analysis of the product ingredient declaration.

Hershey maintained that establishing a U.S. standard of identity for white chocolate would promote honesty and fair dealing in the interest of consumers and build consumer confidence in the food supply by establishing minimal criteria for a class of products that is becoming popular with consumers. According to Hershey, adoption of the suggested standard of identity for white chocolate will also enhance the ability of American manufacturers to compete in world markets. Hershey maintained that a U.S. standard will result in greater consistency in the international regulation of cacao products, while ensuring that domestic consumers are buying and consuming "the real thing."

#### *B. The 1993 CMA Petition*

In all substantive respects, the 1993 CMA petition agrees with the 1992 Hershey petition. In support of its request for a white chocolate standard, CMA noted that the standards of identity for cacao products permit only those products that contain a minimum level of chocolate liquor to be identified as chocolate. CMA maintained that, because there exists a product that consumers identify as "white chocolate," it is essential that the industry define this product, and that FDA establish and enforce a standard of identity for white chocolate products to avoid economic deception and promote honesty and fair dealing in the interest of consumers.

Like Hershey, CMA contended that consumers are being presented with products that often contain low levels of cocoa butter (if any at all) and relatively high levels of noncacao vegetable fats which, except for coatings made with vegetable fats, are not permitted in standardized chocolate products. CMA further stated that products that identify

themselves as "white chocolate," but that do not meet CMA's suggested standard, represent a true deception of the consumer. According to CMA, consumer deception distorts individual purchasing decisions and prevents consumers from satisfying their product preferences. CMA asserted that FDA can reduce or prevent the continuation of such deception by establishing a standard of identity for white chocolate.

CMA further maintained that the absence of a standard of identity for white chocolate denies consumers the benefit of knowing that a white chocolate-type product that they purchase is, indeed, a true cacao product. In the absence of such a standard, the U.S. chocolate industry is unable to provide consumers with an identifiable white chocolate product that meets both their expectations and the industry's definition of quality.

CMA stated that the adoption of their suggested standard would have a positive effect on the marketability of, and competition among, chocolate products. CMA also acknowledged the submission to FDA of a similar petition by Hershey and noted that CMA's suggested white chocolate standard of identity is generally consistent with that in the Hershey petition. CMA further noted that while its suggested standard is generally based on FDA standards of identity for cacao products, the specific minimum levels of cacao fat, milkfat, and total milk solids are based on those found in the European Union (EU) white chocolate standard published in the *Official Journal of European Communities*.

CMA explained that although antioxidants are not permitted in cacao products under the current standards of identity for these foods, they are needed in the proposed white chocolate standard. CMA maintained that in making white chocolate, cocoa butter is typically deodorized to achieve the desired flavor. In the process, the natural antioxidants are removed. Therefore, CMA contended, the addition of antioxidants to white chocolate is necessary to preserve the product flavor.

CMA suggested that because Canada is proposing a standard for white chocolate that is also based on the EU standard, adoption of its proposed standard would increase harmonization of U.S. requirements with those of Canada. Such harmonization, CMA maintained, is consistent with the goals of the North American Free Trade Agreement.

#### *III. The Proposal*

Both petitioners agree that a standard of identity for white chocolate would

promote honesty and fair dealing in the interests of consumers, eliminate a deterrent to firms introducing new products, enhance international marketability of the product, and be consistent with the white chocolate standard of the EU and that proposed by Canada.

The agency finds merit in the petitioners' request and tentatively concludes that creating a standard of identity for white chocolate would promote honesty and fair dealing in the interests of consumers because the standard would eliminate the potential for economic fraud and consumer deception through the substitution of cheaper ingredients for cacao-derived ingredients.

Establishing a standard of identity for white chocolate will alleviate the need for companies to request TMP's to market products bearing the name "white chocolate" that deviate from the standards of identity for other chocolate products or, in lieu of requesting a TMP, crafting identity statements using descriptive names other than "chocolate." A standard also will enhance international marketability of the product and increase harmonization with the EU and Canada.

While the agency tentatively agrees with the petitioners that a standard for white chocolate should be established, it notes that it is reviewing its existing standards of identity in response to the Administration's Regulatory Reinvention Initiative that seeks to streamline Government to ease the burden on regulated industry and consumers. In the Federal Register of December 29, 1995 (60 FR 67492), FDA published an advance notice of proposed rulemaking (ANPRM) in which it requested comments on whether food standards of identity should be retained, revised, or revoked. In the ANPRM, the agency specifically asked for comments on whether, if it institutes a broad rulemaking on reinventing food standards, it is appropriate in the interim to have a moratorium on food standard actions, i.e., on the issuance of TMP's and on the development of new or revised food standard regulations. Several comments submitted by industry to the ANPRM opposed a moratorium on the creation of new standards of identity while the agency is reviewing existing food standards in response to the Regulatory Reinvention Initiative. The comments asserted that a moratorium would disadvantage firms by delaying the introduction of new products and would not be in the consumer's best interest.

Although FDA is reviewing existing food standards in response to the Regulatory Reinvention Initiative, the agency tentatively concludes that there are compelling reasons to establish a standard for white chocolate at this time. First, the number of requests for TMP's for white chocolate has demonstrated to the agency that there is a consumer demand for this product. As discussed in section I. of this document, the agency has granted TMP's for the market testing of up to 166 million lb of product containing white chocolate. Second, the establishment of a standard for white chocolate seemingly will benefit industry by making it easier to introduce new products containing white chocolate. It will eliminate the need for firms to obtain a TMP to market the products and to send labels to the agency for review whenever they wish to market a new product containing white chocolate or a different size product than those allowed by their TMP. Third, as stated above, the establishment of the standard will benefit U.S. firms by enhancing the international marketability of their product. Finally, the adoption of a standard will ease FDA's burden because it will end the flow of paper from firms seeking, or operating under a TMP. Thus, the agency tentatively concludes that establishing a standard of identity for white chocolate will be beneficial to consumers and to industry and will also result in more efficient use of the agency's limited resources.

However, FDA advises that if a standard of identity for white chocolate is established, the agency will review it along with all other standards of identity as part of the Regulation Reinvention Initiative. The standard of identity for white chocolate would be retained, revised, or revoked consistent with decisions regarding other standards of identity for cacao products.

The proposed standard of identity for white chocolate is slightly different from the standards of identity for other chocolate products in part 163. As described in the 1993 CMA petition, safe and suitable antioxidants are needed to help preserve the product's flavor. The agency has no information that shows that the addition of safe and suitable antioxidants to this product should be prohibited. Therefore, FDA is proposing to provide for the use of antioxidants in proposed § 163.124(b)(5).

FDA tentatively concludes that it is reasonable to establish the term "white chocolate" as the common or usual name for the standardized food described below. The public has become familiar with the term "white

chocolate" through the recent market testing of products that consist, in whole or in part, of this food. The agency further tentatively concludes that use of this term will aid consumer recognition of the food and will promote honesty and fair dealing in the interest of consumers by eliminating the potential for economic fraud and consumer deception through the substitution of cheaper ingredients for cacao-derived ingredients. Finally, the agency tentatively concludes that the consumer confusion engendered by the use of alternative names for white chocolate-type confections will also be eliminated, and that the use of the standardized term "white chocolate" in the product name will enhance the international marketability of such products.

Therefore, the agency is proposing to revise part 163 by establishing a standard of identity for white chocolate in new § 163.124. Specifically, FDA is proposing to provide that "white chocolate" have the following description:

1. White chocolate is the solid or semiplastic food prepared by intimately mixing and grinding cacao fat with one or more of the optional dairy ingredients and one or more optional nutritive carbohydrate sweeteners and may contain one or more of the other optional ingredients specified in the standard. White chocolate shall be free of coloring material.

2. White chocolate shall contain not less than 20 percent by weight of cacao fat, not less than 3.5 percent by weight of milkfat, not less than 14 percent by weight of total milk solids, and not more than 55 percent by weight nutritive carbohydrate sweetener.

3. White chocolate may contain the following optional ingredients:

- a. Nutritive carbohydrate sweeteners;
- b. Dairy ingredients:
  - i. Cream, milkfat, butter;
  - ii. Milk, dry whole milk, concentrated milk, evaporated milk, sweetened condensed milk;
  - iii. Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;
  - iv. Concentrated buttermilk, dried buttermilk; and
  - v. Malted milk;
- c. Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1 percent by weight;

d. Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination

impart a flavor that imitates the flavor of chocolate, milk, or butter; or  
e. Antioxidants.

#### IV. Effective Date

To allow companies time to make any mandatory changes, the agency proposes that any final rule that may be issued based on this proposal become effective January 1, 1998. The final rule would apply to affected products initially introduced or initially delivered for introduction into interstate commerce on or after the effective date.

#### V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or raising novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. The agency acknowledges that under some circumstances this proposed rule may have significant impact on a substantial number of small entities. It has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104-121).

#### A. Alternatives

FDA is proposing to establish a standard of identity for white chocolate so that only products meeting the criteria described in the proposal may be called "white chocolate." One alternative is to not establish a standard and allow manufacturers to market products bearing the name "white chocolate" only with TMP's. Another alternative is to establish a standard for white chocolate that is consistent with the standard described in the petitions where the levels of the ingredients are prescribed. A third alternative is to establish a standard of identity for white

chocolate with different criteria than those proposed in the petitions. While the agency has no explicit information on the exact formulations or attributes that consumers associate with the term "white chocolate," the agency has written the proposed standard of identity to be as consistent as possible with the existing standards of identity for chocolate products while making the necessary allowances to accommodate the formulations described in the petitions. FDA requests comments on these and other alternatives to the proposed standard of identity.

#### *B. Benefits*

The largest benefit of this proposed standard of identity for white chocolate is that it will eliminate a manufacturer's need to prepare and submit requests for TMP's in order to market products bearing the name "white chocolate." Another benefit is that it would eliminate the need to divert scarce agency resources to the evaluation of these TMP requests. Currently, manufacturers are required to obtain TMP's to use the term "chocolate" to market products that meet the proposed standard because they deviate from the existing standards of identity for chocolate products. The agency has received more than 1 dozen requests for TMP's for white chocolate in the last year. The establishment of the proposed standard of identity would save hours of manufacturer and FDA time required for the preparation and evaluation of each TMP.

Additionally, the benefits usually attributed to the establishment of standards of identity are reductions in the potential for consumer confusion and deception. Well defined standards of identity, which establish consistent product names, can assist consumers in finding and comparing products by the name of the food. Finally, the proposed standard will establish a new product name that, according to the petitions, is consistent with the name that a majority of consumers are already using to describe this product.

#### *C. Costs*

The establishment of a standard of identity requires that all products that meet the standard bear the standardized name. If there are products that are formulated in accordance with the proposed standard but are not currently marketed under a TMP allowing use of the term "white chocolate," then those products will have to be relabeled. Because "white chocolate" will need to appear on each product's principal display panel, the cost for label changes will depend on the number of products

needing to be relabeled and the amount of time manufacturers are given to complete the label changes. The actual cost of relabeling will be determined largely by the length of time between the date that the proposed rule becomes final and the effective date of the final rule (the compliance period). In general, the large chocolate manufacturers are already marketing their products under TMP's. For small firms the cost of relabeling ranges from \$12,750 with a 6-month compliance period to \$1,550 with a 24-month compliance period. The agency has no information on the number of products that will need to be relabeled. There are approximately 250 firms that produce chocolate products in the United States, however, the number of products that meet the proposed standard of identity is unknown. This proposal will not affect products that do not meet the standard, because they may continue to be produced and marketed as they currently are. FDA is not able to estimate the total cost of this proposal and requests that comments supply information on this issue.

#### *D. Initial Regulatory Flexibility Analysis*

If finalized, this proposed rule will establish a standard of identity for white chocolate. Depending upon the length of the compliance period, this proposal may or may not impose significant compliance costs on industry and there may or may not be a significant impact of these provisions on a substantial number of small businesses. However, because there is some uncertainty related to the costs of compliance, FDA is voluntarily doing this Initial Regulatory Flexibility Analysis. The agency requests comment on this judgment.

FDA believes that the only provision of this proposed rule that may have a significant impact on a substantial number of small businesses is related to the compliance period. There are approximately 250 firms that produce chocolate products (Standard Industry Classification Code 206603) in the United States. Almost all of these businesses have fewer than 500 employees. The agency has no data on the number of products that will meet the proposed standard and that, therefore, may need to be relabeled. The relabeling costs are the primary costs of the rule. Relabeling costs vary inversely to the length of the compliance period. FDA has estimated the compliance costs based on three alternatives for the length of the compliance period.

With a 6-month compliance period the costs to small firms that produce one product that would meet the proposed

standard are estimated to be \$12,750 (\$3,400 for administrative costs, \$3,200 for printing costs, and \$6,150 for costs of lost label inventory). With a 12-month compliance period the costs to small firms that produce one product that would meet the proposed standard are estimated to be \$3,300 (\$1,700 for administrative costs, \$1,100 for printing costs, and \$500 for costs of lost label inventory). With a 24-month compliance period the costs to small firms that produce one product that would meet the proposed standard are estimated to be \$1,550 (\$850 for administrative costs, \$700 for printing costs, and nothing for costs of lost label inventory). The agency requests comments on the impact of the compliance period on small chocolate producers and suggestions for minimizing the impact of this proposed rule on small businesses.

#### *VI. Environmental Impact*

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### *VII. Paperwork Reduction Act*

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements. Thus, there is no "information collection" necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is asking for comment on whether this proposed rule imposes any paperwork burden.

#### *VIII. Comments*

Interested persons may, on or before May 27, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### *List of Subjects in 21 CFR Part 163*

Cacao products, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 163 be amended as follows:

#### **PART 163—CACAO PRODUCTS**

1. The authority citation for 21 CFR part 163 continues to read as follows:

Authority: Secs. 201, 301, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 341, 343, 348, 371, 379e).

2. New § 163.124 is added to subpart B to read as follows:

##### **§ 163.124 White chocolate.**

(a) *Description.* (1) White chocolate is the solid or semiplastic food prepared by intimately mixing and grinding cacao fat with one or more of the optional dairy ingredients and one or more optional nutritive carbohydrate sweeteners and may contain one or more of the other optional ingredients specified in paragraph (b) of this section. White chocolate shall be free of coloring material.

(2) White chocolate contains not less than 20 percent by weight of cacao fat as calculated by subtracting from the weight of the total fat the weight of the milkfat, dividing the result by the weight of the finished white chocolate, and multiplying the quotient by 100. The finished white chocolate contains not less than 3.5 percent by weight of milkfat and not less than 14 percent by weight of total milk solids, calculated by using only those dairy ingredients specified in paragraph (b)(2) of this section, and not more than 55 percent by weight nutritive carbohydrate sweetener.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

- (1) Nutritive carbohydrate sweeteners;
- (2) Dairy ingredients:
  - (i) Cream, milkfat, butter;
  - (ii) Milk, dry whole milk, concentrated milk, evaporated milk, sweetened condensed milk;
  - (iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;
  - (iv) Concentrated buttermilk, dried buttermilk; and
  - (v) Malted milk;
- (3) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1 percent by weight;
- (4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter; or

(5) Antioxidants.

(c) *Nomenclature.* The name of the food is "white chocolate" or "white chocolate coating." When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(4) of this section are used, the label shall bear an appropriate statement, e.g., "Spice added", "Flavored with \_\_\_\_\_", or "With \_\_\_\_\_ added", the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

Dated: January 6, 1997.

Fred R. Shank,  
Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97-5734 Filed 3-7-97; 8:45 am]

BILLING CODE 4160-01-F

#### **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

##### **24 CFR Part 982**

[Docket No. FR-4149-P-01]

RIN 2577-AB73

##### **Section 8 Rental Voucher and Certificate Programs Restrictions on Leasing to Relatives**

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would limit the circumstances under which a landlord could lease a unit with Section 8 certificate or voucher assistance to a relative of the landlord. It would permit such leasing only if an HA determines that the leasing would accommodate a person with disabilities. The rule is intended to reduce the potential for misuse of Section 8 assistance. It would reduce the likelihood of families that have the ability to assist a family member from seeking Federal rental assistance and, thereby, would help to direct scarce Federal financial assistance to the more needy.

**DATES:** Comment due date: May 9, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposed rule to the Office of the General Counsel, Rules Docket Clerk, room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500.

Comments should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying during regular business hours (7:30 a.m. to 5:30 p.m. Eastern time) at the above address.

#### **FOR FURTHER INFORMATION**

**CONTACT:** Gerald Benoit, Director, Operations Division, Office of Rental Assistance, Public and Indian Housing, Department of Housing and Urban Development, Room 4220, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-0477. Hearing or speech impaired individuals may call HUD's TTY number (202) 708-4594 or 1-800-877-8399 (Federal Information Relay Service TTY). (Other than the "800" number, these are not toll-free numbers.)

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Discussion**

Currently, neither the statute nor HUD regulations place any restriction on an owner leasing a unit with Section 8 certificate or voucher assistance to a relative. All parties, of course, would have to meet requirements generally applicable to any certificate or voucher assisted tenancy. These requirements include: the applicant meets income and other eligibility requirements; the applicant is selected in appropriate order from the HA's waiting list; the unit meets housing quality standards, and the rent to the owner is reasonable.

This policy of no restrictions on leasing with assistance to relatives has been in effect since the inception of the Certificate Program in the mid-1970s. Historically, it has been viewed by the Department as consistent with an overarching policy of promoting maximum housing choice for assisted families.

The Department does not have systematic data on the extent to which, or the circumstances under which, owners have been leasing to family members. Nonetheless, it must be recognized that a policy of allowing leasing between closely related individuals creates a potential for misallocation of scarce program resources. It can encourage families that can house family members to seek and obtain Federal assistance that otherwise would be available for more needy families. In short, it can shift, too readily, responsibility for housing a close relative from a relative with available housing or financial resources to the Federal Government.

Recent newspaper articles have described a number of examples of relatives leasing to other relatives with