

(a) A short account of the progress of drug development including a description of studies initiated, ongoing, and completed, and a short summary of the status or results of such studies;

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the MUMS-designated drug status of the product. For example, situations in which testing data demonstrate that the proposed intended use is inappropriate due to unexpected issues of safety or effectiveness.

#### **§ 516.31 Scope of MUMS-drug exclusive marketing rights.**

(a) After conditional approval or approval of an application for a MUMS-designated drug in the dosage form and for the intended use for which MUMS-drug designation has been granted, FDA will not conditionally approve or approve another application or abbreviated application for the same drug in the same dosage form for the same intended use before the expiration of 7 years after the date of conditional approval or approval as stated in the approval letter from FDA, except that such an application can be conditionally approved or approved sooner if, and at such time as, any of the following occurs:

(1) FDA terminates the MUMS-drug designation and associated exclusive marketing rights under § 516.29; or

(2) FDA withdraws or proposes to withdraw the conditional approval or approval of the application for the drug for any reason; or

(3) The sponsor with exclusive marketing rights provides written consent to FDA to conditionally approve or approve another application before the expiration of 7 years; or

(4) The sponsor fails to assure a sufficient quantity of the drug in accordance with section 573 of the act and § 516.36.

(b) If an application for a MUMS drug cannot be approved until the expiration of the period of exclusive marketing of a MUMS-designated drug, FDA will so notify the sponsor in writing.

#### **§ 516.34 FDA recognition of exclusive marketing rights.**

(a) FDA will send the sponsor (or the permanent-resident U.S. agent, if applicable) timely written notice recognizing exclusive marketing rights when an application for a MUMS-designated drug has been conditionally approved or approved. The written notice will inform the sponsor of the

requirements for maintaining MUMS-designated drug exclusive marketing rights for the full 7-year term. This notice will generally be contained in the letter conditionally approving or approving the application.

(b) When an application is conditionally approved or approved for a MUMS-designated drug that qualifies for exclusive marketing rights, FDA will publish this information in the **Federal Register** at the time of the conditional approval or approval. This notice will generally be contained in the notice of conditional approval or approval of the application.

#### **§ 516.36 Insufficient quantities of MUMS-designated drugs.**

(a) Under section 573 of the act, whenever the FDA has reason to believe that sufficient quantities of a conditionally-approved or approved, MUMS-designated drug to meet the needs for which the drug was designated cannot be assured by the sponsor, the FDA will so notify the sponsor of this possible insufficiency and will offer the sponsor the following options, one of which must be exercised by a time that FDA specifies:

(1) Provide FDA information and data regarding how the sponsor can assure the availability of sufficient quantities of the MUMS-designated drug within a reasonable time to meet the needs for which the drug was designated; or

(2) Provide FDA in writing the sponsor's consent for the conditional approval or approval of other applications for the same drug before the expiration of the 7-year period of exclusive marketing rights.

(b) If, within the time that FDA specifies, the sponsor fails to consent to the conditional approval or approval of other applications and if FDA finds that the sponsor has not shown that it can assure the availability of sufficient quantities of the MUMS-designated drug to meet the needs for which the drug was designated, FDA will issue a written order terminating designation of the MUMS drug and the associated exclusive marketing rights. This order will state FDA's findings and conclusions and will constitute final agency action. An order terminating designation and associated exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Such an order will not withdraw the conditional approval or approval of an application. Once terminated under this section, neither designation, nor exclusive marketing rights may be reinstated.

#### **§ 516.52 Availability for public disclosure of data and information in requests.**

(a) FDA will not publicly disclose the existence of a request for MUMS-drug designation under section 573 of the act prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Except as provided in paragraph (d) of this section, upon final FDA action on a request for designation, the public availability of data and information in the request will be determined in accordance with part 20 of this chapter and other applicable statutes and regulations.

(d) In accordance with § 516.28, FDA will make a cumulative list of all MUMS-drug designations available to the public and update such list periodically. In accordance with § 516.29, FDA will give public notice of the termination of all MUMS-drug designations.

#### **Subpart C—[Reserved]**

#### **Subpart D—[Reserved]**

Dated: August 31, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 135**

[Docket Nos. 2003P-0132 and 2000P-1491 (formerly 03P-0132 and 00P-1491)]

#### **Frozen Desserts; Petition to Revoke Standards for Goat's Milk Ice Cream and Mellorine and to Amend Standards for Ice Cream and Frozen Custard, Sherbet, and Water Ices; Petition to Amend Standards for Parmesan and Reggiano Cheese**

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

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the following two petitions have

been filed: A petition requesting that the agency revoke the standards of identity for goat's milk ice cream and mellorine, and amend the standards of identity for ice cream and frozen custard, sherbet, and water ices in numerous respects; and a petition requesting that the agency amend the standard of identity for parmesan and reggiano cheese to decrease the minimum curing time from 10 months to 6 months. The FDA is issuing an advance notice of proposed rulemaking (ANPRM) to request comments to determine whether the action proposed in the petitions would promote honesty and fair dealing in the interest of consumers.

**DATES:** Submit written or electronic comments by December 27, 2005.

**ADDRESSES:** You may submit comments, identified by Docket Nos. 2003P-0132 and 2000P-1491, by any of the following methods:

#### *Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

#### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

**Instructions:** All submissions received must include the agency name and Docket No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Catalina Ferré-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. The International Ice Cream Association (IICA) Petition**

IICA submitted a citizen petition on March 31, 2003, requesting that FDA revoke the standards of identity in part 135 (21 CFR part 135) for goat's milk ice cream (§ 135.115) and mellorine (§ 135.130), amend the current standard of identity for ice cream and frozen custard (§ 135.110), amend the standard of identity for sherbet (§ 135.140), and amend the standard of identity for water ices (§ 135.160).

In its petition, IICA states that its proposed amendments to the frozen desserts standards of identity improve efficiency by bringing these standards of identity up to current technological standards. Specifically, IICA's proposed amendments to the frozen desserts regulations in part 135, establish definitions for the following terms: (1) Ultrapasteurized, (2) milk (to include filtered milk), (3) nonfat milk, (4) milk-derived protein, and (5) milk-derived ingredients. In addition, IICA's proposed ice cream and frozen custard standard would permit, among other things, the use of any safe and suitable milk-derived ingredients as well as milk from other animal sources and would require source declaration when milk other than cow's milk is used (e.g., goat, sheep). IICA's proposed amendments would also provide for "alternate make" procedures and would change the minimum requirements of fat and protein content. For frozen custard, French ice cream, and French custard ice cream, the IICA proposal provides for a minimum of 1.4 percent egg yolk. Further, IICA's proposed amendments would require the use of specific Association of Official Analytical Chemists International (AOAC) analytical methods for determination of fat and protein content. Finally, IICA's proposed amendments would provide

that the manufacturer may determine whether a natural or artificial flavor provides the characterizing flavor for purposes of labeling and would provide for collective common or usual names for some milk-derived ingredients.

IICA also proposes that many of the proposed changes to the ice cream and frozen custard standard be applied to the sherbet standard. IICA's proposed amendments to the sherbet standard included allowing for use of the following: (1) Any safe and suitable milk-derived ingredients; (2) milk from animals other than cows, whose source would be reflected in the product name; (3) safe and suitable sweeteners; and (4) "alternate make" procedures. IICA also proposes minimum and/or maximum requirements for milk-derived protein, milkfat and fruit content.

IICA's proposed amendments to the water ices standard provide for the use of safe and suitable ingredients and optional fruit-characterizing ingredients and remove the requirement that the product is aerated or stirred while freezing.

FDA is publishing this document in accordance with section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(1)), which directs the Secretary of Health and Human Services to publish proposals made by petition to amend or repeal a dairy product food standard, as long as the petition includes reasonable grounds for the action requested, and to provide interested persons with an opportunity to present their views. FDA tentatively finds that IICA's petition presents reasonable grounds. Therefore, FDA requests comment on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers.

##### *A. Grounds for the Suggested Changes for Ice Cream and Frozen Custard, Goat's Milk Ice Cream, Mellorine, Sherbet, and Water Ices Standards*

IICA asserts that the proposed changes to the frozen desserts standards of identity would increase efficiency by reducing unnecessary regulatory burdens and would allow manufacturers to take advantage of new manufacturing and ingredient technologies. IICA states that these changes would allow manufacturers to reduce costs and to pass these savings on to consumers. IICA contends that the proposed changes would result in a finished product nutritionally equivalent to products manufactured according to the current standard; therefore, no economic harm or consumer deception would result from the proposed amendments. IICA also maintains that

the proposed amendments to the standards would reduce FDA's expenses because newly developed ingredients could be used without having to amend the standards for each change while still ensuring consumer health and safety.

IICA's proposed amendments to the ice cream and frozen custard and sherbet standards provide for the use of safe and suitable milk-derived ingredients rather than providing an extensive list of ingredients permitted as is done in the current standards. IICA asserts that this would streamline the current standards. Moreover, IICA notes that its proposed amendment to the ice cream and frozen custard standard, which provides for seven categories of milk derived ingredients to be declared on labels under common names, would allow manufacturers to adjust their formulas based on ingredient availability within each class of ingredients without the need to print new labels. In addition, IICA asserts, that because the nutritional profile of ice cream is based on a protein equivalent, consumers will not be deceived by the proposed categories because the final product will be nutritionally equivalent regardless of the individual ingredient within the class that is used.

In its petition, IICA proposes removing the maximum 25-percent restriction on whey solids in ice cream and frozen custard to allow for any combination of safe and suitable dairy-derived ingredients. IICA contends that, by removing the 25-percent cap on whey solids, more whey proteins can be used to satisfy the minimum protein requirement. In addition, IICA asserts that whey proteins have a higher nutritional value than other milk proteins and higher protein digestibility than milk.

Further, IICA proposes replacing the minimum nonfat milk solids requirements contained in the current ice cream and frozen custard and sherbet standards with a minimum milk-derived protein percentage based on the proportionate amount of fat in the foods. IICA contends that a milk-derived protein requirement is easier to measure, and thus, the requirement is easier to enforce than a minimum nonfat milk solids requirement.

In its petition, IICA proposes a new provision for "alternate make" in the manufacture of ice cream and frozen custard and sherbet. IICA states that the proposed amendment for an "alternate make" provision in certain frozen desserts is consistent with the alternate make provisions in cheese standards. IICA further states that the "alternate make" provision would be confined to

those processes that produce a finished product that is equivalent to the product made by traditional procedures regarding physical, chemical (including nutritional) and organoleptic properties. IICA also states that including an "alternate make" provision would provide flexibility to use improvements in food technology in the manufacture of ice cream, frozen custard, and sherbet without having to amend the standard.

In its petition, IICA also proposes removing the current ice cream and frozen custard standard requirement regarding the amounts of fruits, fruit juice and nut meats present, at or below which an artificial flavor simulating a characterizing flavor is deemed the predominant flavor for purposes of naming the product. Also, IICA proposes changing the levels of fruit content in sherbet at or below which the artificial flavor is deemed to predominate over the fruit ingredient in characterizing the flavor of the product. IICA proposes changing these levels from a minimum of 2-percent for citrus sherbets, 6-percent for berry sherbets, and 10-percent for sherbets prepared with other fruits to a 2-percent minimum content for all fruits to allow greater flexibility in developing new and exotic flavors. IICA asserts that intense flavors, when used in combination with bland flavors, overpower the bland flavors if used at the 10-percent level currently required for sherbet prepared with fruits other than citrus and berry.

IICA also proposes to delete the standard for goat's milk ice cream and instead to provide for declaration of the source-animal for milk in ice cream when the milk is from an animal other than cow. IICA states that having separate standards of identity is unnecessarily duplicative and limits possibilities for the use of milk from other source animals.

In addition, IICA proposes to revoke the mellorine standard. IICA asserts that mellorine is not in great demand. IICA further states that, if the mellorine standard is revoked, frozen dairy desserts formulated by replacing milkfat with vegetable fat may still be manufactured but would be labeled with a common or usual name that is more descriptive, such as "frozen dessert" or "frozen dairy dessert," if the milk solids predominate. IICA contends that these names would allow manufacturers more flexibility to address consumer demand and more accurately describe the product.

Finally, IICA proposes to provide for the use of safe and suitable ingredients in the water ices standard rather than providing an extensive list of

ingredients permitted as is done in the current standard. IICA also proposes the use of optional fruit-characterizing ingredients in water ices.

#### *B. Matters of Particular Interest to FDA Regarding IICA's Petition*

FDA requests that interested persons submit data and information concerning the need for, and the appropriateness of, revoking the standards for goat's milk ice cream and mellorine and amending the standards for ice cream and frozen custard, sherbet, and water ices as proposed by IICA. FDA specifically requests comment and supporting data, as appropriate, on the following provisions set forth in the petition:

1. The use of filtered milk in the making of frozen desserts;
  2. The use of any safe and suitable milk-derived ingredients in the manufacture of frozen desserts;
  3. The use of milk from source animals other than cows in the making of ice cream and frozen custard and sherbet;
  4. The use of "alternate make" procedures in the manufacture of ice cream and frozen custard and sherbet;
  5. A minimum weight requirement of 4 pounds per gallon for reduced fat ice cream;
  6. A minimum milk-derived protein requirement based on the amount of fat;
  7. The removal of the requirement of the maximum 25-percent restriction on whey solids in ice cream and frozen custard;
  8. The removal of the requirements for the amounts of fruits, fruit juices, and nut meats needed to determine if an artificial flavor simulating a characterizing flavor is the predominant flavor when naming an ice cream or frozen dessert product, and providing that the manufacturer may determine whether the natural or artificial flavor ingredients provide the characterizing flavor of the product for purposes of labeling;
  9. The establishment of categories of ingredients to be declared on labels under common names for ice cream and frozen custard;
  10. The removal of the restrictions on ingredients in goat's milk ice cream;
  11. The use of a 2-percent minimum level of fruit content in sherbet.
- After reviewing the comments received, FDA will further evaluate the need for, and appropriateness of, each of the amendments requested by IICA and will decide what further actions are appropriate. To facilitate comment, in the following paragraphs FDA discusses some of the amendments requested by IICA.

IICA proposes amending the current standards of identity for frozen desserts (part 135) to provide for a definition of "milk" that includes "filtered milk" for use in the manufacture of frozen desserts. IICA also proposes allowing categories of ingredients to be declared on labels under a common name. For example, IICA proposes allowing filtered milk in dried and liquid form to be labeled as "milk." Currently, filtered milk is not allowed in the manufacture of frozen desserts. FDA solicits comment on the need to amend the standard to provide for the use of filtered milk in the making of frozen desserts, and whether all forms or only specific forms of filtered milk should be permitted. FDA also solicits comments on the importance of filtered milk for the basic nature and essential characteristics of ice cream. The basic nature of the food is directly related to consumer expectations and beliefs about the food. The essential characteristics of a food are those that define or distinguish a food or describe the distinctive properties of a food. Although the essential characteristics of a food may contribute to achieving the basic nature of that food or may be relevant to meeting certain consumer expectations about the food, they differ from the basic nature of the food in that consumers may not be aware of the essential characteristics that make the food what it is.

The standards for ice cream and frozen custard, sherbet, and water ices proposed by IICA permit the use of any safe and suitable ingredient added to accomplish a specific function. FDA recognizes the need for food standards to permit flexibility in food technology, as long as that technology does not alter the basic nature or essential characteristics of the food. The existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose. Under the provisions of (part 130) 21 CFR 130.10, standardized foods may be modified to contain nutrients not specifically permitted by the relevant standard of identity and to make an expressed nutrient content claim defined by FDA regulation. FDA also notes that flexibility in the use of ingredients for a functional purpose may be achieved by specifying the ingredients by functional use category, e.g., "emulsifiers" or "preservatives," rather than by listing the specific ingredients. FDA seeks comment on the proposed amendment permitting the use of any safe and suitable ingredient to

accomplish a specific function in the manufacture of frozen desserts.

IICA proposes replacing the minimum nonfat milk solids requirement contained in the current ice cream and frozen custard and sherbet standards with a minimum milk-derived protein requirement based on the amount of fat because the nonfat milk solids cannot be differentiated from other solids in the foods. FDA seeks comments on the following: (1) The necessity and appropriateness of this proposed amendment; (2) whether this amendment would be consistent with the basic nature and essential characteristics of ice cream and frozen custard and sherbet; (3) whether the proposed minimum milk-derived protein content requirement should replace the current minimum nonfat milk solids requirement or be implemented in addition to the current requirement for a minimum nonfat milk solids; and (4) how replacing a minimum nonfat milk solid requirement with a minimum milk-derived protein requirement would affect the compositional and nutritional profile of the product.

In its petition, IICA proposes to provide for the use of any safe and suitable milk-derived ingredient, such as components or fractions of milk including, milkfat, milk protein, milk sugars and minerals in the manufacture of frozen desserts. IICA asserts this would allow for the use of newly developed ingredients without having to amend the standard. FDA solicits comment on the appropriateness of this proposed amendment, and on whether it would be consistent with the basic nature and essential characteristics of frozen desserts.

IICA proposes creating categories of ingredients to be declared on labels under a common name to allow manufacturers to adjust their formulas based on ingredient availability without the need to print new labels. In addition, IICA asserts that the milk-derived ingredients in the proposed categories are nutritionally and functionally equivalent when used in frozen desserts, and therefore, consumers would not be deceived by the proposed categories because the final product would be nutritionally equivalent regardless of the individual ingredient within the class that is used. We seek comment on the appropriateness of this amendment requested by IICA. Specifically, FDA seeks comment on whether consumers would be confused by category names on frozen desserts when compared to other dairy products or non-dairy products and whether category names as

described in the petition would inform consumers about the specific ingredients that are used to make the food. In addition, if considered appropriate, should collective names be permitted for all the categories in the petition? Why or why not? Would consumers be confused, misled or deprived of material information?

IICA also proposes including a new provision for "alternate make" procedures in the manufacture of frozen desserts. IICA states that this provision is necessary to provide flexibility to permit the use of improvements in food technology without having to amend the standards. However, IICA did not submit information about any current "alternate make" procedures. We request information describing "alternate make" procedures in the making of ice cream currently available and on the consistency of those procedures with the basic nature and essential characteristics of ice cream. In addition, if "alternate make" procedures are allowed, is the framework currently used for cheese standards appropriate for ice cream?

The current standard for ice cream and frozen custard has a maximum 25 percent restriction on whey solids. The IICA proposed standard removes the maximum 25-percent restriction on whey solids in ice cream and frozen custard to allow for any combination of safe and suitable dairy-derived ingredients, provided the proposed minimum milk-derived protein content is satisfied. FDA requests comment on the following: (1) The appropriateness of removing the maximum 25-percent restriction on whey solids to allow for any combination of safe and suitable dairy-derived ingredients, provided the minimum milk-derived protein content is satisfied; (2) any concerns with using whey protein as a main ingredient in the manufacture of ice cream and frozen custard; (3) any information that supports the contention in the petition that whey protein currently used in the market is of higher nutritional value, higher quality and protein digestibility than protein currently used in ice cream and custard; and (4) whether the use of more than 25-percent whey ingredients is consistent with the basic nature and essential characteristics of ice cream and frozen custard.

IICA proposes removing the amounts of fruits, fruit juices, and nut meats in the ice cream and frozen custard standard used to determine whether an artificial flavor simulating a characterizing flavor is the predominant flavor when naming the product. IICA states that under its proposed amendments, the manufacturer would

determine whether the natural or artificial flavor ingredients provides the characterizing flavor of the product and would label the product accordingly. In its petition, IICA also proposes changing the requirements in sherbet for the amounts of fruit or fruit juice from a minimum of 6-percent for berry sherbets and a minimum of 10-percent for sherbets from other fruits to a minimum of 2-percent. FDA implemented the current requirement for determining whether the fruit ingredient or artificial flavor is the characterizing flavor of the food in 1964 when a final rule on frozen desserts was published. We recognize that there have been advancements in food technology, and we question whether this requirement is still necessary. Specifically, FDA seeks comment on the following: (1) Whether standard amounts of fruits, fruit juices, and nut meats are needed to determine if an artificial flavor simulates a characterizing flavor when naming the product; (2) other alternatives to the current requirements in the standard and to the petitioner's proposed amendment that would ensure products are labeled in a way that would not be misleading to consumers; and (3) whether it is appropriate to allow manufacturers to determine whether the fruit ingredient or artificial flavor predominates in characterizing the flavor of the product and label the product accordingly.

IICA proposes amending the current standard of identity for sherbet to provide for a 2-percent minimum fruit content. Under the current sherbet standard, the minimum amount of fruit content is not less than 2-percent for citrus sherbets, 6-percent for berry sherbets, and 10-percent for sherbets prepared with other fruits. FDA solicits comment on changing the varying minimum levels of fruit content in sherbet to a 2-percent minimum content for all types of fruit and on what technical impact such an amendment would have on the finished product. FDA also solicits comments on the consistency of the existing and proposed minimum fruit content levels with the basic nature and essential characteristics of citrus sherbet, berry sherbets, and other relevant sherbets.

FDA further solicits comments on whether any other requirements that are currently in the standards for frozen deserts including ice cream, frozen custard, water ice, and sherbet are not needed to ensure that products bearing these terms on their labels conform to the basic nature and essential characteristics of these products. FDA also requests information on the costs associated with any unnecessary

elements or on the cost savings associated with eliminating them.

FDA solicits comments on the impact of the recommended changes in food standards on manufacturers of frozen deserts and, in particular, on small manufacturers. The relevant impacts include both direct effects, such as labeling costs and changes in production costs, as well as indirect effects, such as any impact on the sales of products affected by these changes.

FDA solicits comments on any paperwork burden from generating the recommended changes in food standards.

In addition, while we ask for comment on specific petition provisions, we would accept comment on other aspects of the frozen desserts standards. Please submit copies of supportive data along with your comments.

On May 20, 2005, FDA published a proposed rule entitled "Food Standards; General Principles and Food Standards Modernization" (hereinafter referred to as the "food standards proposal") (70 FR 29214) that proposes to establish a set of general principles to modernize food standards. While we recognize that we are proposing this advance notice of proposed rulemaking (ANPRM) before the food standards proposal is finalized, we encourage the public to consider the proposed general principles in the food standards proposal when commenting on this ANPRM.

### C. International Ice Cream Association Requested Amendments

The requested amendments of the ice cream and frozen custard standard, the sherbet standard, and the water ices standard submitted by IICA are set forth in the following paragraphs. The following language is as suggested by IICA; FDA has made only minor nonsubstantive changes. FDA will further evaluate the need and appropriateness of these regulations proposed by IICA following the receipt of public comments.

IICA's suggested standard of identity for ice cream and frozen custard is as follows:

#### Subpart A—General Provisions § 135.3 Definitions.

For the purposes of this part:

(a) A pasteurized mix is one in which every particle of the mix has been heated in properly operated equipment to one of the temperatures specified in the table in this section and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be

equivalent thereto in microbial destruction):

Temperature	Time
155 °F	30 min.
175 °F	25 sec.
180 °F	15 sec.
191 °F	1 sec.
204 °F	0.05 sec.
212 °F	0.01 sec.

(b) Ultra-pasteurized when used to describe a dairy product means that such product shall have been thermally processed at or above 280 °F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

(c) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry whole milk. Water in sufficient quantity to reconstitute concentrated and dry forms may be added.

(d) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk and nonfat dry milk. Water in a sufficient quantity to reconstitute concentrated forms may be added.

(e) *Milk-derived protein* means casein and/or whey protein(s) and its constituents, fractions, hydrolysates or polymers derived from milk.

(f) *Milk-derived ingredients* means any ingredient derived from milk or any component or fraction of milk such as milkfat, milk proteins defined in 135.3(e), milk sugars and minerals. [42 FR 19127 at 19132, April 12, 1977]

Subpart B—Requirements for Specific Standardized Frozen Desserts  
§ 135.110 *Ice Cream and frozen custard.*

(a) *Description.* (1) Ice cream is produced by freezing, while stirring, a pasteurized aerated mix consisting of safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. Safe and suitable non-dairy

derived ingredients that serve a useful function may be added. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

(2) Ice cream is a food prepared by the procedures set forth in paragraph (a) of this section, or by any other procedure which produces a finished product which has essentially the same physical, chemical and organoleptic characteristics.

(3) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon, except where the ice cream is a fat reduced ice cream as defined by applicable sections of § 130.10, reduced fat ice cream shall weigh not less than 4.0 pounds per gallon. Ice cream contains not less than 10-percent milkfat, nor less than 2.95 percent milk-derived protein, except that when it contains milkfat above 10-percent minimum, it may contain the following

milkfat, milk-derived protein levels specified in the table in this section. The protein to meet the minimum milk-derived protein requirement shall be provided by milk-derived ingredients, and shall have a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) as determined by the method prescribed in the most recent edition of AOAC Approved Methods for the following protein levels.

Percent Milkfat	Minimum Percent Milk-Derived Protein
10	2.95
11	2.66
12	2.36
13	2.07
14	1.77

Except that when one or more bulky flavors are used, the weight of milkfat is not less than 10-percent of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat less than 7.5 percent of the weight of the finished food, nor is the milk-derived protein content less than 1.8 percent of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard, french ice cream or french custard ice cream shall contain at a minimum 1.4 percent egg yolk solids by weight of the finished food: Provided, however, that when bulky flavors are added the egg yolk solids content of frozen custard, french ice cream or french custard ice cream may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12-percent. A product containing egg yolk solids of at least 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (c) of this section.

(4) When calculating the minimum amount of milkfat and milk-derived protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or

cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Methods of analysis.* (1) The fat content shall be determined by using the Mojonnier method prescribed in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method. Copies may be obtained from AOAC INTERNATIONAL, First Union National Bank Lockbox, PO Box 75198, Baltimore, MD 21275-5198, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/code\\_of\\_federal\\_regulation/ibr\\_locations.html](http://www.archives.gov/code_of_federal_regulation/ibr_locations.html).

(2) The protein content shall be determined by one of the following methods: "Nitrogen Official Final Action," Kjeldahl Method, Section 16.285, or Dye Binding Method, Section 16.286 found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method.

(3) PER shall be determined by the method: "Biological Evaluation of Protein Quality—Official Final Action, sections 43.212-43.216" found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method.

(c) *Nomenclature.* (1) When the food is made exclusively from cows milk, the name of the food is "ice cream;" except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard" or "french ice cream" or "French custard ice cream." When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is "  milk ice cream," or as appropriate, "frozen   milk custard," "french   milk ice cream," "french custard   milk ice cream" (the blank being filled in with the name of the milk source animal, e.g., "goat's milk ice cream"). When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase "made with   milk" (the blank being filled in with name(s) of all milk source animals).

(2)(i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla," in letters not less than one-half the height of the letters used in the words "ice cream."

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the

words "ice cream," followed by the word "flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "Vanilla flavored," or "Peach flavored," or "Vanilla flavored and Strawberry flavored."

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream," preceded by "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla," or "artificially flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry."

(3)(i) If the food is subject to the requirements of paragraph (c)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial\_\_ flavor added," the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint by less than one-half gallon, not less than 10-point on packages containing at least one-half gallon by less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: Provided, however, that where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: And provided further, that if the finished product contains more than one flavor of ice cream subject to the requirements of this

paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added."

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor."

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in § 169.3(c) of this chapter.

(ii) In determining the characterizing flavor of products other than those in paragraph 5(i) of this section, it shall be incumbent on the manufacturer to conclude whether the natural or artificial flavor intensity predominates. The manufacturer shall determine which flavor is present in the greatest intensity and label the product accordingly. For example, strawberry ice cream consists of a combination of natural strawberries and artificial strawberry flavor. If the natural strawberry component was stronger in flavor intensity it would be deemed to predominate, and the ice cream would be labeled "strawberry flavored." If, on the other hand, the artificial strawberry flavor component was stronger in flavor intensity, the artificial flavor component would be deemed to predominate, and the ice cream would be labeled "artificially flavored strawberry" or "artificial strawberry."

(iii) In the case of two or more fruits or fruit juices, or nut meats or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is not sufficient to characterize the flavor, the products would be labeled as "a blend of artificial and natural fruit and/or nut flavoring."

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this standard shall govern each flavor of ice cream comprising the combination.

(7) If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with

the requirements of part 105 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, except that:

(1) Milk, concentrated milk, evaporated milk, dried milk, filtered milk in liquid and dried form, may be declared as "milk."

(2) Nonfat milk, skim milk, condensed skim milk, evaporated skim milk, nonfat dried milk, filtered nonfat milk in liquid and dried form may be declared as "nonfat milk."

(3) Buttermilk, sweet cream buttermilk, condensed sweet cream buttermilk and dried sweet cream buttermilk may be declared as "buttermilk."

(4) Cream, whey cream, dried cream, plastic cream (sometimes known as concentrated milkfat) may be declared as "cream."

(5) Butter, butter oil, and anhydrous milk fat may be declared as "butter fat."

(6) Milk-derived protein such as casein, whey protein and its constituents, fractions, hydrolysates or polymers derived from milk, except filtered milk, may be declared as "milk proteins."

(7) Whey, concentrated whey, reconstituted whey and dried whey may be declared as "whey."

(e) Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by § 101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

#### § 135.140 *Sherbet.*

(a) *Description.* (1) Sherbet is produced by freezing, while stirring, an aerated pasteurized mix consisting of safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredient used. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. Safe and suitable non-dairy derived ingredients may be added that serve a useful function. Sherbet is sweetened with safe and suitable sweeteners and is characterized by the addition of one or more of the optional fruit-characterizing ingredients specified in paragraph (b) of this section or one or more of the optional nonfruit-characterizing ingredients specified in paragraph (c) of this section.

(2) Sherbet is a food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure, which produces a finished product, which has essentially the same physical, chemical and organoleptic characteristics.

(3) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2-percent. The milk-derived protein content is not less than 0.295 percent and not greater than 1.18 percent in the case of 1 percent milkfat or not greater than 0.89 percent in the case of 2-percent milkfat.

(b) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2-percent. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) *Optional nonfruit characterizing ingredients.* Optional nonfruit characterizing ingredients may be used.

(d) *Nomenclature.* (1) The name of each sherbet is as follows:

(i) When the food is made exclusively from cows milk, the name of each fruit sherbet is “\_\_sherbet,” the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) When the food is made exclusively from cows milk, the name of each nonfruit sherbet is “\_\_sherbet,” the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, “peppermint,” except that if the characterizing flavor used is vanilla, the name of the food is “\_\_sherbet,” the blank being filled in as specified by § 135.110(e)(2) and (5)(i).

(iii) When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is specified as in paragraphs (d)(1)(i) and (ii) of this section, except that the phrase “\_\_milk” shall immediately precede the word “sherbet” (the blank

being filled in with the name of the milk source animal, e.g., “goat’s milk ice cream”). When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase “made with \_\_milk” (the blank being filled in with the name(s) of all milk source animals).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be “artificially flavored.”

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be “artificial and natural flavoring added.”

(iii) The label shall designate artificial coloring by the statement “artificially colored,” “artificial coloring added,” “with added artificial coloring,” or “\_\_, an artificial color added,” the blank being filled in with the name of the artificial coloring used.

(e) *Characterizing flavor(s).* Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraphs (d)(2)(i) and (d)(2)(ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word “sherbet” may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(f) *Display of statements required by paragraph (d)(2).* Except as specified in paragraph (e) of this section, the statements required by paragraph (d)(2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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

§ 135.160 *Water Ices.*

(a) *Description.* Water ices are the foods each of which is prepared from safe and suitable ingredients and complies with all the provisions of § 135.140(a)(1) and (a)(2), except that stirring while freezing or aerating is not required, and the mix need not be pasteurized, and no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

(b) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) *Optional nonfruit characterizing ingredients.* Optional nonfruit characterizing ingredients may be used.

(d) *Nomenclature.* The name of the food is “\_\_ice,” the blank being filled in, the same manner as specified in §§ 135.140(d)(2)(i) and (ii) and (iii)(e), (f), and (g), as appropriate.

## II. Kraft Foods, Inc. (Kraft Foods) Petition

Kraft Foods submitted a citizen petition dated August 28, 2000, requesting that FDA amend the current standard of identity in part 133 (21 CFR part 133) for parmesan and reggiano cheese (hereinafter parmesan cheese) (§ 133.165). In its petition, Kraft Foods proposed that the minimum curing time for parmesan cheese be reduced from 10 months to 6 months, by changing the last sentence of § 133.165(a) from “[i]t is cured for not less than 10 months” to “[i]t is cured for not less than 6 months.”

FDA is publishing this document in accordance with section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 371(e)(1)), which directs the Secretary of Health and Human Services to publish proposals made by petition to amend or repeal a dairy food standard, so long as the petition includes reasonable grounds for the action requested, and to provide interested persons with an opportunity to present their views. FDA tentatively finds that Kraft Foods’ petition presents reasonable grounds. Therefore, FDA requests comment on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers.



### A. Grounds for the Suggested Change to the Parmesan Cheese Standard

In the **Federal Register** of February 21, 1973 (34 FR 4710), FDA found that reducing the minimum curing time of parmesan cheese from 14 months to 10 months increased productivity, improved product consistency, and reduced production costs with no material disadvantage to consumers. Based on these findings, the standard of identity for parmesan cheese was amended to reduce the required curing time from a minimum of 14 months to a period of not less than 10 months. According to Kraft Foods, technology has continued to improve and parmesan cheese is now able to be produced within a curing period of 6 months. Kraft Foods submits that consistent with the 1973 findings, FDA should, for essentially the same reasons, amend the parmesan cheese standard to reduce its required curing period to not less than 6 months.

In April of 1999, Kraft Foods was issued a temporary marketing permit (TMP) for market testing its "100% Grated Parmesan Cheese" cured for 6 months (64 FR 16743, April 6, 1999). In November of 1999, FDA issued Sartori Foods Corp. a TMP to market test its 6-month cured "Grated Parmesan Cheese" (64 FR 60820, November 8, 1999). On August 28, 2000, Kraft Foods submitted to FDA an application for extension of its TMP accompanied by a petition to amend the parmesan cheese standard. As stated in the **Federal Register** (65 FR 83040, December 29, 2000), an extension was granted to allow for continuous data collection on consumer acceptance of the products while the agency took action on the petition to amend the standard.

In its petition, Kraft Foods states that its make procedure involves the use of an improved enzyme technology but is otherwise consistent with the make procedure and curing techniques Kraft Foods has followed for many years. Using commercially-available safe and suitable enzymes (21 CFR 133.165(b)) and the current make procedure, Kraft Foods states that it is possible to produce fully-cured parmesan cheese suitable for grating in 6 months, rather than the 10-month minimum curing time currently required by the standard of identity. Kraft Foods states that the modern manufacturing procedures, commercially-available enzymes, and modern equipment that it uses are generally available to enable any knowledgeable processor through the utilization of adequate scientific research and experimentation to produce parmesan cheese conforming

with the standard of identity in the shorter 6-month curing time.

According to its petition, through periodic evaluation of product, Kraft Foods determined that parmesan cheese cured for 6 months is physically and organoleptically equivalent to current parmesan cheese cured for 10 months. In addition, Kraft Foods conducted organoleptic evaluations through consumer taste panels that confirmed that the grated 6-month cured product is considered by consumers to be equivalent (i.e., in taste, texture and cooking properties) to grated parmesan cheese currently available to consumers. Kraft Foods also states that the shortened curing time has no effect on the nutrition profile of the product.

Although not specifically addressed in its petition, Kraft Foods briefly addressed the issue of safety in its TMP application. In its TMP application, Kraft Foods stated that its 6-month cured parmesan cheese product is "just as wholesome and nondeleterious as other such cheeses available to consumers." FDA relied on the representations made in the petitioner's application in approving the TMP, and we tentatively concluded, at that time, that the shortened time period would not affect the safety of the product, i.e., there is not a safety concern.

Kraft Foods states that there is a substantial economic benefit from reducing the curing time from 10 months to 6 months. Kraft Foods states that the proposed amendment would reduce the cost of inventory and reduce losses from damage during the additional 4-month holding period; therefore, the shorter curing time may also make it possible for manufacturers to devote some of their production resources to the manufacture of other cheese products, thereby maximizing the use of plant resources and increasing production efficiencies. Kraft Foods also maintains that the substantial curing/holding times required to produce parmesan cheese effectively mean that the cost of entry into the parmesan cheese production business is quite high. Kraft Foods notes that in the long run, reducing the curing time for this product will significantly reduce the costs of entry into the business, in turn, creating the opportunity for greater competition, which benefits consumers, who are best served by a marketplace in which there is more, rather than less, competition.

### B. Matters of Particular Interest to FDA Regarding Kraft Foods' Petition

FDA requests that interested persons submit data and information concerning the need for, and the appropriateness of,

amending the standard for parmesan cheese. FDA specifically requests comment on whether the proposed amendment will affect the basic nature, organoleptical, safety or physical properties of parmesan cheese. FDA requests comments, especially from small business, on Kraft Food's statement that this change will reduce cost barriers to entry into the marketplace.

### C. Kraft Foods Requested Amendment

The requested amendment of the parmesan cheese standard submitted by Kraft Foods is set forth in the following paragraph:

§ 133.165 *Parmesan and reggiano cheese.*

(a) \* \* \* It is cured for not less than 6 months.

\* \* \* \* \*

FDA will evaluate the need and appropriateness of the proposed regulation following the receipt of public comments.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Authority

This advance notice of proposed rulemaking is issued under sections 201, 401, 403, 409, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, and 379e), and under the authority of the Commissioner of Food and Drugs, as redelegated to the Director, Center for Food Safety and Applied Nutrition.

Dated: September 16, 2005.

**Leslye M. Fraser,**

*Director, Office of Regulations and Policy,  
Center for Food Safety and Applied Nutrition.*  
[FR Doc. 05-19194 Filed 9-26-05; 8:45 am]

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