credit union duties of the Director of the Office of Examination and Insurance § 790.2(b)(6)(ii)) is deleted. There are several references in the corporate credit union regulation (12 CFR part 704) to the Director, Office of Examination and Insurance. These references (indicating who corporate credit unions should submit reports and requests to) are all changed to the Director, Office of Corporate Credit Unions. Section 704.16 of the corporate regulation is entitled "Effective Date." Part 704 was made effective in 1992 and this section sets forth procedures for a temporary waiver from the effective date. Since there are no longer any outstanding waivers, the provisions relating to waiver are deleted.

The Office of Information Systems has been renamed the Office of Technology and Information Services. The description of this office has been updated. The appropriate changes in name and description are made to § 790.2(b)(10).

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires the NCUA to prepare an analysis to describe any significant economic impact any regulation may have on a substantial number of small credit unions (primarily those under $1 million in assets). The types of changes made by this rule have no economic impact on credit unions. These are merely housekeeping changes. Therefore, the NCUA Board has determined and certifies that, under the authority granted in 5 U.S.C. 605(b), this final rule will not have a significant economic impact on a substantial number of small credit unions. Accordingly, the Board has determined that a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

This final rule does not change any paperwork requirements.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. Since these are housekeeping changes only, there is no effect on state interests.

List of Subjects in 12 CFR Parts 704 and 790

Credit unions.

By the National Credit Union Administration Board on September 6, 1994.

Becky Baker,

Secretary of the Board.

Accordingly, for the reasons set out in the preamble, 12 CFR parts 704 and 790 are amended as set forth below.

PART 704—CORPORATE CREDIT UNIONS

1. The authority citation for part 704 continues to read as follows:

Authority: 12 U.S.C. 1762, 1766(a), 1781, and 1789.

§§ 704.10, 704.11, 704.13, 704.16, Appendix B to Part 704 [Amended]

2. Remove the phrase "Director, Office of Examination and Insurance" and add, in its place, the phrase "Director, Office of Corporate Credit Unions" in the following places (the phrase appears three times in § 704.10(b)(2)):

(a) § 704.10(b)(2);
(c) § 704.11(a)(1);
(b) § 704.11(a)(2);
(c) § 704.13(c);
(d) Section c. of Appendix B.

3. Section 704.16 is amended by removing the second, third and fourth sentences.

PART 790—DESCRIPTION OF NCUA; REQUESTS FOR AGENCY ACTION

4. The authority citation for part 790 continues to read as follows:

Authority: 12 U.S.C. 1766, 1789, and 1795f.

5. Section 790.2 is amended by moving paragraph (b)(6)(ii); by redesignating paragraph (b)(6)(iii) as paragraph (b)(6)(ii); by revising paragraph (b)(10) and adding a new paragraph (b)(16) as follows:

§ 790.2 Central and region office organization.

* * * * *

(b) * * *

(10) *Office of Technology and Information Services.* The Director of the Office of Technology and Information Services has responsibility for the management and administration of NCUA's information resources. This includes the development, maintenance, operation, and support of information systems which directly support the Agency's mission, maintaining and operating the Agency's information processing infrastructure, responding to requests for releasable Agency information, and insuring all related material security and integrity risks are recognized and controlled as much as possible.

* * * * *

(16) *Office of Corporate Credit Unions.* The Director, Office of Corporate Credit Unions, manages NCUA's corporate credit union program in accordance with established policies and the corporate regulation. The Director's duties include directing chartering, examination and supervision programs to promote and assure safety and soundness; managing NCUA's corporate resources to meet program objectives in the most economical and practical manner, and maintaining good public relations with public, private and governmental organizations, corporate credit union officials, credit union organizations, and other groups which have an interest in corporate credit union matters.

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 135

[Docket No. 88P-0251]

Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to remove the standard of identity for ice milk; to amend the standard of identity for ice cream and frozen custard to provide for the use in these foods of safe and suitable sweeteners and of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; and to amend the standard of identity for ice cream and frozen custard to provide for the optional use of hydrolyzed milk proteins as stabilizers in the food at a level not to exceed 3 percent by weight to ice cream mix containing not less that 20 percent total milk solids, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. To ensure consistency with the removal of the standard of identity for ice milk and the changes in the standard of identity for

ice cream and frozen custard, FDA also is removing the standard of identity for goat's milk ice milk and making comparable changes in the standard of identity for goat's milk ice cream, which cross-references the standard of identity for ice cream and frozen custard. FDA finds that these actions will promote honesty and fair dealing in the interest of consumers. FDA is also requiring that all sweeteners other than nutritive carbohydrate sweeteners used in these foods be declared as part of the name of the food. This requirement will terminate after a period of 3 years. After that time, the use of these sweeteners will only have to be reflected in the ingredient statement for these products.

DATES: Effective September 14, 1995; written objections and requests for a hearing by October 14, 1994. Compliance with this regulation may begin on September 14, 1994.

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

FOR FURTHER INFORMATION CONTACT: Margaret E. Cole, 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 January 6, 1993 (58 FR 520), FDA published a proposed rule: (1) To remove the standards of identity for ice milk (§ 135.120 (21 CFR 135.120)) and goat's milk ice milk (§ 135.125 (21 CFR 135.125)); and (2) to amend the standards of identity for ice cream and frozen custard (§ 135.110 (21 CFR 135.110)) and, by cross-reference, goat's milk ice cream (§ 135.115 (21 CFR 135.115)) to provide for the use in these foods of safe and suitable sweeteners and of skim milk that may be concentrated and from which part or all of the lactose has been removed by a safe and suitable procedure. The agency also requested information on the use of other milk-derived protein ingredients such as milk protein hydrolysates. Interested persons were given until March 8, 1993, to comment.

II. Comments and the Agency's Responses

In response to the proposal, FDA received 46 letters, each containing one or more comments from food companies, ingredient suppliers, industry trade associations, State government agencies, and consumers. All of the comments favored the removal of the standards of identity for ice milk (§ 135.120) and goat's milk ice milk (§ 135.125). One comment addressed an issue (i.e., the need for uniformity in the size, style, and color of the type used in food labeling) that is outside the scope of this proposal and that will not be discussed here.

Several comments suggested modifications in, or were opposed to, various provisions of the proposal to amend the standards of identity for ice cream (§ 135.110) and, by cross-reference, goat's milk ice cream (§ 135.115). A summary of these comments and the agency's responses follow

A. Safe and Suitable Ingredients

1. Sweeteners

FDA proposed (58 FR 520 at 523 and 524) to amend the standards of identity for ice cream and, by cross-reference, goat's milk ice cream to permit the use of safe and suitable sweeteners (§ 135.110(a)(1) and § 135.115(a)) as long as the presence of sweeteners other than nutritive carbohydrate sweeteners is declared by their common or usual name on the principal display panel of the label as part of the statement of identity, and as long as the labeling of ice cream products sweetened with such sweeteners complies with the applicable provisions of § 105.66 (21 CFR 105.66) (proposed § 135.110(e)(7) and proposed § 135.115(c)(2)). The agency specifically requested comments on the need for, and appropriateness of, these proposed changes. The comments generally supported permitting alternative sweeteners (safe and suitable sweeteners other than nutritive carbohydrate sweeteners) in ice cream. Some comments, however, questioned the proposed declaration requirements for alternative sweeteners. These comments are addressed below.

1. Several comments opposed the requirement that the presence of alternative sweeteners be declared in the statement of identity, as provided in proposed § 135.110(e)(7). These comments stated that the existing regulations for the labeling of specific alternative sweeteners adequately inform consumers of the presence of alternative sweeteners in foods. These comments also expressed the view that there is no need to establish special front panel labeling requirements for alternative sweeteners in ice cream, and that such a requirement would contribute to label clutter on products in which manufacturers use more than one alternative sweetener in their formulation.

These comments noted that the proposed declaration requirement singles out ice cream for special labeling that is not applied to other standardized foods, and that such a requirement also singles out alternative sweeteners for special labeling that is not applied to other ingredients, including nutritive carbohydrate sweeteners. These comments further argued that milk and dairy components, not sugar, are the defining characteristics of ice cream. These comments expressed the view that use of the name "ice cream" with a nutrient content claim in the statement of identity, and the obligatory referral statement that directs consumers to the information panel, would signal to consumers that the product differs from the traditional standardized food.

FDA proposed to require that alternative sweeteners be declared by their common or usual name on the principal display panel of the label as part of the statement of identity because of the agency's tentative conclusion that ice cream sweetened with alternative sweeteners is a distinctly different product than that sweetened with nutritive carbohydrate sweeteners. The agency proposed this requirement to ensure that ice cream sweetened with alternative sweeteners is clearly distinguishable from the traditional food, and so that consumers who want to avoid ice cream that contains alternative sweeteners will be able to do so. In the proposal, the agency tentatively concluded that it is necessary to inform consumers of the presence of alternative sweeteners in ice cream under sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n) and 343(a)).

Based on its consideration of the comments, the agency has confirmed its view that consumers should be advised through labeling on the principal display panel of the label or other labeling, including restaurant menus and ice cream shop and parlor listings, when ice cream products are made with sweeteners other than nutritive carbohydrate sweeteners. Currently, such products are labeled as "frozen desserts" or by some other name that is not confusingly similar to the standardized term "ice cream." When the amendments to §§ 135.110 and 135.115 set forth below become effective, products that differ from traditional ice cream in that they contain alternative sweeteners would be subject to being labeled simply as "ice cream" but for the clarification of the differences between these products and

traditional ice cream that the agency has decided to require.

FDA does not agree that the existing regulations for the labeling of specific alternative sweeteners adequately inform consumers of the presence of these sweeteners in ice cream. It is true that manufacturers must declare the presence of aspartame and of saccharin in a food on the food label. The label of ice cream that contains aspartame will have to bear either on the principal display panel or on the information panel in a prominent and conspicuous manner the statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE," as specified in § 172.804(e)(2) (21 CFR 172.804(e)(2)). The label of ice cream that contains saccharin will have to bear in a conspicuous place on such label and labeling as proximate as possible to the name of such food, the statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS," as specified in section 403(o)(2) of the act (21 U.S.C. 343(o)(2)). In neither case, however, is there a specific requirement that the statements appear on the principal display panel of the ice cream label as is the case under § 135.110(f)(7) (proposed as § 135.110(e)(7)). Further, there is no legal or regulatory requirement for special labeling statements on the principal display panel to inform consumers that ice cream contains other alternative sweeteners (e.g., sorbitol, acesulfame K). Without § 135.110(f)(7), there need not be anything on the principal display panel to call consumers' attention to the presence of alternative sweeteners in ice cream. Thus, FDA finds that there would not be adequate notice of the presence of these sweeteners without this provision.

FDA does not agree that the declaration requirement singles out ice cream sweetened with alternative sweeteners for special labeling. FDA has established a number of standards of identity specifically for artificially sweetened versions of traditional foods, such as canned fruits, so that the artificially sweetened versions of these foods are distinguishable from their traditional counterparts that are sweetened with nutritive carbohydrate sweeteners. These artificially sweetened versions of traditional foods are identified as such through label declaration on the principal display panel.

As an example, the standard of identity in § 145.170 (21 CFR 145.170) for canned peaches provides for the addition of safe and suitable nutritive carbohydrate sweeteners (e.g., corn sirup, invert sugar sirup, sugar, dried glucose sirup, or cane sirup) to the packing medium. The name of this food is "peaches" as prescribed in § 145.170(a)(4). By contrast, the standard of identity in § 145.171 (21 CFR 145.171) for artificially sweetened canned peaches conforms to the definition and standard of identity in § 145.170 for canned peaches except that it provides for the use of water artificially sweetened with saccharin, with sodium saccharin, or with a combination of both, as the packing medium. The name of this food is "artificially sweetened peaches."

Traditionally, sugar (or other nutritive carbohydrate sweeteners), as well as milk and cream (or dairy products of equivalent composition), defines the food known as "ice cream." In establishing the standard of identity for ice cream, the findings of fact (August 8, 1950, 15 FR 5112 at 5114) gave the following definition of ice cream:

> Ice cream is the common and usual name of the frozen product made from cream or a mixture of milk and cream (or a combination of dairy products of equivalent composition), sweetened with sugar or other suitable sweetening agent, and containing natural or imitation flavorings or other food ingredients, such as cocoa, fruit, and nuts, to characterize it as a kind of ice cream.

Although the findings of fact stated that sugar is the most common sweetening agent in ice cream, the findings of fact also stated that a number of other nutritive carbohydrate sweeteners (e.g., dextrose, invert sugar, corn sirup, maple sirup, honey, brown sugar) are suitable for sweetening ice cream.

Based on the foregoing, the agency believes that consumers have traditionally understood that "ice cream" is a food that is sweetened with nutritive carbohydrate sweeteners. The agency is adopting §§ 135.110(f)(7) and 135.115(c)(2) to ensure that consumers will be able to distinguish the traditional food that is sweetened with nutritive carbohydrate sweeteners from ice cream sweetened with alternative sweeteners. The common or usual name of the latter food is "ice cream sweetened with ————————," the blank being filled in with the common or usual name of any alternative sweeteners used in the food.

FDA advises that, as a consequence of this action, modified ice cream products made in conformance with the general definition and standard of identity in § 130.10 (21 CFR 130.10) that are named by use of a nutrient content claim and the standardized term, and that contain alternative sweeteners, must include the common or usual names of these sweeteners in their statement of identity, e.g., "reduced fat ice cream sweetened with ————————," the blank being filled with the common or usual name of any alternative sweeteners used in the food.

The agency finds that §§ 135.110(f)(7) and 135.115(c)(2) will provide for adequate notice to consumers that safe and suitable sweeteners other than nutritive carbohydrate sweeteners are present in the ice cream or goat's milk ice cream, and that the information required under these provisions is necessary to allow consumers to make informed purchasing decisions in the marketplace. Thus, FDA concludes that this action will promote honesty and fair dealing in the interest of consumers, and the agency is amending these regulations accordingly, as set forth below.

FDA concludes, however, that labeling to distinguish ice cream products sweetened with alternative sweeteners from those sweetened with nutritive carbohydrate sweeteners will not be necessary after consumers have become aware of the fact that some ice cream products are made with nutritive carbohydrate sweeteners, and others with alternative sweeteners, and have had a period of time to become familiar with such foods. Thus, the regulations set out below (§§ 135.110(f)(7) and 135.115(c)(2)) only require that the name of the alternative sweeteners be included as part of the name of the food for 3 years following the effective date of the regulation. At the end of 3 years, this requirement will terminate, and the presence of alternative sweeteners will only have to be declared as part of the ingredient list. FDA believes that 3 years is an adequate amount of time for people to become aware that "ice cream" may be made with either nutritive carbohydrate sweeteners or alternative sweeteners, and thus that it is necessary to check the ingredient list. Three years represented the amount of time necessary for "canola oil" to become the accepted common or usual name for low-erucic acid rapeseed oil (see 50 FR 3755, January 21, 1985 and 53 FR 52652, December 29, 1988). Based on this precedent, the agency finds that a similar amount of time is appropriate here.

2. One comment objected to the proposed labeling requirement that ice cream sweetened with alternative sweeteners be labeled to comply with the requirements of § 105.66.

In the proposal, FDA noted that foods that are sweetened with one or more artificial sweeteners are foods for special dietary use under § 105.3(a)(2).

The agency proposed in § 135.110(e)(7) for ice cream, and in § 135.115(c)(2) for goat's milk ice cream, to require that when these foods are sweetened with alternative sweeteners, they must be labeled to comply with the requirements of § 105.66 because FDA anticipated that these foods would be represented for special dietary use because of their usefulness in helping to reduce or maintain body weight. Such foods must comply with the labeling requirements of § 105.66 (i.e., they must bear special labeling statements such as "low calorie" and "reduced calorie").

FDA acknowledges that the requirements prescribed in § 105.66 may not always apply to the labeling of ice cream sweetened with alternative sweeteners. There may be instances in which ice cream sweetened with alternative sweeteners will not purport to be, or will not be represented to be, for special dietary use because of its usefulness in reducing or maintaining body weight. For instance, a manufacturer may replace all of the nutritive carbohydrate sweeteners in ice cream with alternative sweeteners but not reduce the fat content sufficiently for the food to be "reduced calorie," or a manufacturer may replace some of the nutritive carbohydrate sweeteners in ice cream with alternative sweeteners but not reduce the level of nutritive carbohydrate sweeteners sufficiently for the food to be "reduced calorie." Therefore, even though the ice cream is sweetened with alternative sweeteners, it would not qualify for the use of terms such as "low calorie" or "reduced calorie" or another comparative caloric claim in compliance with part 101 because the manufacturer has not reduced the fat or carbohydrate levels in the food sufficiently to permit the use of such terms on the food label. The agency recognizes that, in such instances, the food need not be labeled in compliance with § 105.66. However, in instances in which ice cream sweetened with alternative sweeteners does purport to be, or is represented, for special dietary use because of its usefulness in reducing or maintaining weight, it must bear special label statements in accordance with § 105.66. If ice cream sweetened with alternative sweeteners is represented for special dietary use because of its usefulness in the diet of diabetics, the food must be labeled to comply with the requirements of § 105.67.

Therefore, to reflect these facts, FDA has revised proposed § 135.110(e)(7) (redesignated as § 135.110(f)(7)) to delete the statement that ice cream sweetened with safe and suitable sweeteners other than nutritive carbohydrate sweeteners must be labeled to comply with the requirements of § 105.66 and to state instead: "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." In addition, the agency has made a similar revision to § 135.115(c)(2) for goat's milk ice cream.

3. One comment expressed concern that FDA would require ingredients that are not found in traditional ice cream, such as safe and suitable sweeteners other than nutritive carbohydrate sweeteners, to be identified by an asterisk in the ingredient statement on the label of ice cream in accordance with the general definition and standard of identity in § 130.10.

This comment is incorrect. In § 130.10, FDA established requirements for foods named by use of a nutrient content claim and a standardized term. The comment specifically refers to the requirement in § 130.10(f)(2) that ingredients used to produce such a food, but that are not provided for in the standard of identity for the traditional food that the new food resembles, and for which it substitutes, be identified with an asterisk in the statement of ingredients. The agency is amending the ice cream standard in § 135.110(a)(1) to provide for the use of safe and suitable sweeteners, both nutritive and nonnutritive, in ice cream. Thus, safe and suitable sweeteners other than nutritive carbohydrate sweeteners are now provided for in the standard of identity for "ice cream." As a result, § 130.10(f)(2) does not apply to safe and suitable alternative sweeteners, such as aspartame or acesulfame K, used in a modified ice cream product. As a result, in making a "reduced calorie" ice cream, manufacturers who replace some or all of the nutritive carbohydrate sweeteners in the food with one or more safe and suitable alternative sweeteners will not need to identify these safe and suitable sweeteners with an asterisk in the ingredient statement on the label of the modified product although they will need to identify these sweeteners on the principal display panel for the next 3 years.

2. Dairy Ingredients

The standard of identity for ice cream (§ 135.110) provides for the optional use of one or more of the specific dairy ingredients listed in § 135.110(b). In view of the wide range of optional dairy ingredients listed by name or by the process by which they are derived in § 135.110(b), FDA invited comments on whether the specific names should be deleted from § 135.110(b), and whether the standard should be amended to provide for the use of any safe and suitable dairy ingredient (58 FR 520 at 525). In addition, the agency specifically requested that any comments supporting the use of a collective term such as "dairy ingredient" provide a definition for the term that will facilitate proper interpretation of any regulation that may result.

4. Several comments requested that FDA revise § 135.110(b) to provide for the use of any safe and suitable dairy ingredient. The comments stated that the current list of specific optional dairy ingredients unnecessarily limits the types of dairy ingredients that may be used in ice cream products and impedes the development of innovative technologies for the production of new ingredients for use in ice cream products.

One comment suggested that the term "dairy ingredient" be defined as an ingredient processed by any safe and suitable process from cow's or goat's milk. Another comment merely stated that the definition of "dairy ingredient" should include ingredients that have the same physical composition that occurs in natural milk, as well as ingredients that have been modified physically but that have not been substantially altered chemically.

In establishing the standard of identity for ice cream, the findings of fact (15 FR 5112 at 5114) stated that ice cream is essentially a sweetened milk and cream product, and that it is made from cream, or a mixture of milk and cream (or a combination of dairy products of equivalent composition) and sugar or other suitable sweetening agent. The ice cream standard included a specific listing of optional dairy ingredients that FDA considered to be suitable for use in ice cream. These dairy ingredients were restricted to the following: Cream, butter, milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, skim milk, concentrated (evaporated or condensed) skim milk, superheated condensed skim milk, sweetened condensed skim milk, dried skim milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, and sweetened skim milk which has been concentrated and from which part of the lactose has been removed after crystallization. However, in establishing the ice cream standard, FDA also recognized that certain ingredients that were derived in part from milk, but that were no longer equivalent in composition to milk, were not suitable for use in ice cream because they were so changed that they had lost the characteristics of milk and cream,

including a large proportion of their water-soluble vitamins and minerals (15 FR 5112 at 5115). Thus, to ensure the integrity of ice cream, the agency did not provide for the use of such ingredients in the food.

Since the standard of identity for ice cream was first published, technological advances in the dairy industry have increased the number, variety, and availability of ingredients derived from dairy sources. These developments have made less and less obvious the boundary between dairy ingredients and other ingredients that may be derived from dairy sources but that are not dairy ingredients.

Over the years, the list of optional dairy ingredients permitted in ice cream has gradually grown to include various forms of milk, skim milk, cream, butter, and whey products, although there are certain restrictions on the level of use of the last type of ingredients (i.e., any whey and modified whey products used can contribute, singly or in combination, not more than 25 percent by weight of the total milk solids content of the finished food (§ 135.110(b)). In addition, the ice cream standard permits the optional use of caseinates with certain restrictions on their levels of use in the food (i.e., they may be added to ice cream mix containing not less than 20 percent total milk solids (§ 135.110(c)), but FDA does not consider caseinates to be dairy ingredients.

FDA finds that to ensure the integrity of ice cream, any definition for the term "dairy ingredient" must differentiate between dairy ingredients and other ingredients that may be derived from dairy sources but that are not suitable as replacements for the milk solids in ice cream, or that are suitable only when used in limited amounts because they are no longer equivalent in composition to milk and cream. In the manufacture of these dairy-derived ingredients such as caseinates, changes are made that make them different from milk and cream. For example, in making caseinates, the calcium normally present in the naturally occurring casein of milk may be replaced with sodium. In addition, if casein or caseinates alone are used to replace the protein of milk, the protein quality of the ice cream may be decreased because the protein efficiency ratio for whole milk protein is higher than that for casein.

The definitions for "dairy ingredient" that were suggested by the comments do not distinguish dairy ingredients from dairy-derived ingredients. Without an adequate definition for this term, FDA is hesitant to expand the list of optional ingredients permitted for use in ice cream in § 135.110(b) to allow for "dairy ingredients" because of the problems that use of the term will engender. Thus, the agency is retaining the list of optional dairy ingredients that may be used in ice cream and is not providing for the general category designation of safe and suitable dairy ingredients in § 135.110(b).

3. Milk Protein Hydrolysates

In the **Federal Register** of January 22, 1991 (56 FR 2149), FDA published an advance notice of proposed rulemaking (ANPRM) announcing the filing of petitions that requested, among other things, the establishment of new standards of identity for "lowfat ice cream" and "nonfat ice cream" and a change in the name of the standardized food known as "ice milk" to "reduced fat ice cream." Interested persons were given until March 25, 1991, to comment.

One comment received in response to the ANPRM requested that FDA amend the ice cream standard in § 135.110 to provide for the use of safe and suitable milk-derived protein ingredients other than caseinates, provided that the milk solids content minimums required by the standards are otherwise met (58 FR 520 at 525). The comment stated that these "other milk protein ingredients" include milk protein hydrolysates (enzyme-modified milk protein) and milk protein isolates (caseinates and whey protein co-isolates). The comment maintained that the use of milk proteins other than caseinates contributes to aeration of frozen lowfat dairy desserts, thereby improving the body and texture of these products, and that their use will not reduce the nutritional value of standardized dairy products. It further stated that these ingredients are safe and suitable for use in other nonstandardized foods such as frozen yogurt, coffee whiteners, infant formulas, fortified cereals, and medical foods.

In the proposal, FDA acknowledged that milk protein hydrolysates are generally recognized as safe (GRAS) and are now used in many foods (58 FR 520 at 525). The agency specifically invited comments on the nature of, and the need for, milk protein hydrolysates in ice cream; on the proposed levels of use for these ingredients; on their suitability to perform technical functions in the food; and on any possible adverse effects from their use. The agency stated that it would consider providing for the use of these ingredients in any final regulation that resulted from the proposal if the comments that it received on this issue adequately supported the need for these ingredients in ice cream.

FDA already provides for the optional use of modified whey products, which would include whey protein isolates, as well as for the optional use of caseinates, in ice cream within the limitations set forth in the ice cream standard. The ice cream standard in § 135.110(b) permits the use of modified whey products that are GRAS for use in the food, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Further, the ice cream standard permits the optional use of caseinates in ice cream mix containing not less than 20 percent total milk solids.

5. One comment suggested that FDA permit the optional use of safe and suitable milk-derived proteins, such as milk protein hydrolysates, in ice cream at levels of 1 to 3 percent. Concerning the nature of milk protein hydrolysates, the comment stated that these products are produced by light enzymatic hydrolysis of casein; that they are high in protein (85 percent); and that they have the same nutritional value as the caseinates from which they are derived. The comment stated that milk protein hydrolysates may be used in ice cream to stabilize the food, i.e., to improve its body and texture; to enhance aeration; and to impart resistance to heat shock. The comment also noted that, in addition to the nonstandardized foods listed previously, milk protein hydrolysates have been used in nonstandardized frozen desserts and confectionery nougats. The comment stated that, while these milk protein hydrolysates provide a similar degree of stabilization as nondairy optional ingredients such as vegetable gums, they are nutritionally superior to those ingredients.

FDA acknowledges that hydrolyzed milk proteins, like vegetable gums, may be used to stabilize foams in foods. In addition, FDA recognizes that they also may be used to enhance aeration and to improve body and texture of products such as nougats and frappes. These ingredients are also generally recognized as safe for use in infant formulas, as well as in other food products. Thus, the agency finds that it is appropriate to provide for their use as stabilizers in ice cream. Therefore, the agency is revising the ice cream standard to permit the optional use of hydrolyzed milk proteins, in addition to optional caseinates, in ice cream when the milk solids content minimum provided for in the standard is met.

Accordingly, the agency is amending § 135.110 by revising paragraph (a) and

adding new paragraph (d) to provide for the optional use of hydrolyzed milk proteins as stabilizers. Based upon the information submitted with the comment on this matter, FDA is providing in § 135.110(d) that hydrolyzed milk proteins may be used at a level not to exceed 3 percent by weight of ice cream mix containing not less that 20 percent of total milk solids (see § 135.110(a)(2)). Any whey or modified whey products contained in the milk protein hydrolysates must fall within the limitations in § 135.110(b) on the total level of whey products in ice cream; that is, singly or in combination, they must not contribute more than 25 percent by weight of the total nonfat milk solids content of the finished food.

Because the comment did not submit any information concerning the use of hydrolyzed milk proteins in goat's milk ice cream, the agency is not providing for their use in goat's milk ice cream in § 135.115.

FDA advises that all protein hydrolysates used in foods must be declared in the list of ingredients by a common or usual name that is specific to the ingredient and that includes the identity of the food source from which the protein was derived. Thus, when hydrolyzed milk proteins are used in ice cream, the declaration of these ingredients on the food label shall comply with the requirements in 21 CFR 102.22. "Hydrolyzed casein" and "hydrolyzed whey protein" would be acceptable common or usual names for products derived from casein or whey protein, whereas "hydrolyzed milk protein" would not be an acceptable name.

B. Lactose Reduction in or Removal from Dairy Ingredients by Alternate Technologies

One comment received in response to the ANPRM requested that FDA revise § 135.110(b) to replace the phrase "skim milk that has been concentrated and from which part of the lactose has been removed by crystallization" with "skim milk [that] may be concentrated and from which part of the lactose has been removed by crystallization, ultrafiltration, or other approved technologies." In the proposal, FDA tentatively found that it would be appropriate to amend the ice cream standard to permit the addition of concentrated skim milk from which part of the lactose has been removed by ultrafiltration. The agency stated that it also appeared to be appropriate to provide for the removal of part or all of the lactose by any safe and suitable procedure in order to give manufacturers the opportunity to use state-of-the-art processing technologies as long as the nutritional quality of the resulting food is not detrimentally affected. It stated that this approach will minimize the need to revise the standard should other acceptable procedures be developed for lactose reduction or removal at a later date. Accordingly, FDA proposed to amend § 135.110(b) in the ice cream standard to provide for the addition to the food of skim milk that may be concentrated and from which part or all of the lactose has been removed by a safe and suitable procedure.

6. All of the comments on this provision supported it. One comment, however, requested that ultrafiltration for lactose reduction be extended to other suitable dairy ingredients because skim milk is not the only milk-based dairy ingredient that can be processed by ultrafiltration to remove lactose.

FDA recognizes that ultrafiltration can be used to remove part or all of the lactose from milk-based dairy ingredients other than skim milk. However, in the proposal, the agency did not foreshadow any changes in the ice cream standard to provide for the use of ultrafiltration to remove part or all of the lactose from any optional dairy ingredient listed in § 135.110(b) other than "skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure." Therefore, the modification in § 135.110 requested by this comment is outside the scope of this rulemaking. Persons interested in providing, in ice cream, for the use of additional ingredients that are processed by ultrafiltration to remove lactose may petition the agency to amend the standard.

Therefore, FDA is amending § 135.110(b) of the ice cream standard, as proposed, to allow for the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food.

C. Additional Comments

7. One comment suggested an alternative scheme of nomenclature for ice cream products based on percentage milkfat. The comment suggested that products bearing the term "nonfat" would contain 0 percent milkfat; products bearing the term "lowfat," greater than 0 but less than 3 percent milkfat; products bearing the term "reduced fat," 3 to 7 percent milkfat; and products bearing the name "ice cream," greater than 7 percent milkfat.

This request is outside the scope of the proposal. In the **Federal Register** of January 6, 1993, FDA published a number of final rules establishing food labeling regulations that, in part, were intended to eliminate consumer confusion by establishing definitions for nutrient content claims. In one of these final rules (58 FR 2302), FDA established uniform, consistent definitions for a number of nutrient content claims, including terms for specific fat content claims, and prescribed the specific labeling that must accompany these claims. Terms for specific fat content claims such as "nonfat," "lowfat," and "reduced fat" are defined in § 101.62. In defining terms for specific nutrient content claims, the agency carefully considered each claim to ensure that it would be meaningful to consumers.

In another final rule (58 FR 2431), FDA amended its general provisions for food standards to provide a general definition and standard of identity for foods named by the use of a nutrient content claim defined in part 101 (such as "fat free") in conjunction with a traditional standardized name (e.g., "ice cream"). In accordance with § 130.10, specific fat content claims defined in § 101.62 may be used in conjunction with the standardized term "ice cream" for foods that resemble and substitute for ice cream but that contain less fat (both milkfat and total fat) than traditional ice cream.

Thus, the agency has addressed in separate rulemakings (58 FR 2302 and 58 FR 2431) the types of nutrient content claims that can be used to indicate the amount of fat present in foods, including ice cream products. Further, in this final rule, the agency is removing the standard of identity for ice milk, so that a reduced fat ice cream product that complies with the existing standard of identity for ice milk no longer needs to be labeled "ice milk" and may now be labeled as "reduced fat ice cream."

FDA notes that the percentage milkfat basis for the labeling of ice cream products suggested by the comment is inconsistent with the definitions that the agency has established in its food labeling regulations. Further, the agency believes that the adoption of the suggested alternative scheme of nomenclature for ice cream products could result in consumer confusion about the nature of the food. Therefore, FDA concludes that an alternative scheme of nomenclature for ice cream products, as suggested by the comment, would neither promote uniformity and consistency in the food labeling nor minimize confusion among consumers. Thus, the agency is not making the requested change in the regulations set out below.

8. One comment stated that under existing FDA regulations, frozen dairy products containing 7 to 10 percent milkfat have no standard of identity.

This comment is no longer correct now that the regulation (58 FR 2431) amending the general provisions for food standards to prescribe a general definition and standard of identity for foods named by the use of a nutrient content claim in conjunction with a traditional standardized name has been finalized. Under § 130.10, FDA-defined nutrient content claims for fat content, such as "reduced fat," "lowfat," and "nonfat," can be used in conjunction with the name of a traditional standardized food such as "ice cream" for foods that resemble and substitute for ice cream but that contain less milkfat than traditional ice cream. Therefore, manufacturers may be able to use an appropriate term such as "reduced fat" in conjunction with the standardized name "ice cream" to name ice cream products containing greater than 7 percent but less than 10 percent milkfat, provided that the use of the term complies with § 130.10 and is not false or misleading to consumers. For example, if the manufacturer's regular vanilla ice cream contains 12 percent milkfat, and the manufacturer reduces the fat level of the product by 25 percent, the new version of the product would contain 9 percent milkfat, which falls in the range of milkfat that the comment mentioned (i.e., greater than 7 percent but less than 10 percent). The manufacturer would be able to label the new version of the product with the term "reduced fat" because the product would contain 25 percent less fat per serving than the manufacturer's regular vanilla ice cream.

9. FDA received from a law firm a request for an advisory opinion (Docket No. 93A–0493), dated December 10, 1993, as to whether a frozen dessert product that contains less than 2 percent milkfat and more than 2 percent total fat may be labeled as "reduced fat ice cream." The law firm represents a company that desires to avoid using the name "ice milk" on the label of its product.

Before issuance of this final rule, "ice milk" was defined in § 135.120 as a frozen dessert that contained more than 2 percent milkfat and not more than 7 percent milkfat. With the issuance of the January 1993 final rules, however, a frozen dessert product that contained less than 2 percent milkfat and more than 2 percent total fat, such as that described by the law firm, could have been eligible to be labeled as "reduced fat ice cream" in accordance with § 130.10(a), because it contained less than 2 percent milkfat, but provided that: (1) Any additional fat (above the 2 percent maximum level for milkfat) in the food was there as a component of a flavoring constituent, e.g., fat from nut meats, butterscotch, or chocolate, and not as a replacement of milkfat, and (2) the food was made in compliance with the provisions of § 130.10. The product described in the request was outside the scope of the ice milk standard and would have had to comply with the provisions of § 130.10(b), (c), and (d) with respect to nutrients, performance characteristics, permitted ingredients, and labeling. FDA notes that replacement of the milkfat of ice cream with fats from other sources is contrary to § 130.10(d)(2) because it would alter the dairy character of the food.

If the product described in the request complied with § 130.10, it would have been named, "reduced fat" or "low fat" ice cream. The product would have qualified for the use of the "reduced fat" claim, as defined in § 101.62(b)(4), as part of its name because the total level of fat contained in the product would have been at least 25 percent less fat than ice cream. On the other hand, the product could have borne the "low fat" claim as defined in § 101.62(b)(2) as part of its name if it contained less than 3 grams of total fat per reference amount customarily consumed.

The agency points out that now, with the removal of the ice milk standard in this final rule, the foregoing is still the case except that modified ice cream products that contain levels of milkfat within the range of that previously prescribed by the standard of identity for ice milk (i.e., more than 2 percent but not more than 7 percent) may also be labeled as "reduced fat ice cream," provided that these products comply with the provisions of § 130.10.

III. Conclusions

After review and consideration of the comments received in response to the proposal, FDA concludes that no evidence or information has been presented that would provide a basis for altering the agency's tentative determination that it should remove the standards of identity for ice milk (§ 135.120) and goat's milk ice milk (§ 135.125), and that it should amend the standards of identity for ice cream (§ 135.110) and goat's milk ice cream (§ 135.115) to provide for the use in the food of safe and suitable sweeteners and of skim milk that may be concentrated and from which part or all of the lactose has been removed by a safe and suitable procedure.

Therefore, in this final rule, FDA is removing the standards of identity for ice milk (§ 135.120) and goat's milk ice milk (§ 135.125) as proposed and amending the standards of identity for ice cream (§ 135.110) and goat's milk ice cream (§ 135.115) as proposed with the following exceptions: (1) Ice cream sweetened with alternative sweeteners, or goat's milk ice cream sweetened with alternative sweeteners, needs to bear labeling in accordance with the requirements of part 105 only if the food purports to be or is represented for special dietary use; (2) the name of the alternative sweetener need only be included as part of the name of the food on the principal display panel of the label for a period of 3 years; and (3) hydrolyzed milk proteins may be used as optional stabilizers in ice cream at a level not to exceed 3 percent by weight in ice cream mix containing not less that 20 percent total milk solids, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food.

In addition, FDA has made other minor editorial revisions in the text of the final rule for internal consistency. The agency deleted the language "or may not" from the last sentence in § 135.110(a)(1) of the ice cream standard and redesignated § 135.110(d) through (f) of the ice cream standard as § 135.110(e) through (g).

Because this rulemaking involves the removal and amendment of standards for dairy products, it is subject to the formal rulemaking procedures of section 701(e) of the act (21 U.S.C. 371(e)). Section 701(e) of the act, unlike the informal rulemaking procedures of section 701(a) of the act, requires that the agency provide an opportunity for objections to the final rule. If any objection raises issues of material fact, the agency is to hold a formal evidentiary hearing on those issues.

IV. Analysis of Impacts

FDA has examined the impact of this final rule to amend the standards of identity for ice cream and goat's milk ice cream and to repeal the standards of identity for ice milk and goat's milk ice cream in 21 CFR part 135 as required by Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts and equity). The Regulatory Flexibility Act (Pub. L. 96–354) requires that the

agency analyze options for regulatory relief for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that this final rule will not have a significant impact on a substantial number of small businesses.

V. Environmental Impact

FDA has previously considered the environmental effects of this rule as announced in the proposed rule. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 14, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection for which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

List of Subjects in 21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 135 is amended as follows:

PART 135—FROZEN DESSERTS

1. The authority citation for 21 CFR part 135 is revised to read as follows:

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

2. Section 135.110 is amended by revising paragraphs (a)(1) and (b), by redesignating paragraphs (d) through (f) as paragraphs (e) through (g), and by adding new paragraphs (d) and (f)(7) to read as follows:

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided for in paragraph (d) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; 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. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

* * * * *

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part-skim milk; nonfat dry milk; sweet cream buttermilk; condensed sweet cream buttermilk; dried sweet cream buttermilk; skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate; and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1*N* NaOH, and it has a Ph value in the range of 8.0 to 8.3.

* * * * *

(d) *Optional hydrolyzed milk proteins.* One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less that 20 percent total milk solids, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label shall comply with the requirements of § 102.22 of this chapter.

* * * * *

(f) * * *

(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. 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.

* * * * *

3. Section 135.115 is amended by revising paragraph (a), by redesignating the text of paragraph (c) as paragraph (c)(1), and by adding new paragraph (c)(2) to read as follows:

§ 135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in § 135.110 for ice cream, and complies with all the provisions of § 135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates and hydrolyzed milk proteins may not be used; and paragraphs (f)(1) and (g) of § 135.110 shall not apply.

* * * * *

(c) * * *

(2) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "goat's milk ice cream" but in any case no smaller than one-sixteenth of an inch. 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.

* * * * *

§ 135.120 [Removed]

4. Section 135.120 *Ice milk* is removed from subpart B.

§ 135.125 [Removed]

5. Section 135.125 *Goat's milk ice milk* is removed from subpart B.

Dated: September 7, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–22646 Filed 9–13–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 175

[Docket No. 91F–0359]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of (η^5-cyclopentadienyl)(η^6-isopropylbenzene)iron(II) hexafluorophosphate as a photoinitiator in adhesives for use in food-contact articles. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective September 14, 1994; written objections and requests for a hearing by October 14, 1994.

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

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 8, 1991 (56 FR 50726), FDA announced that a food additive petition (FAP 1B4285) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188. The petition proposed that the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of iron(+), (η^5-2,4-cyclopentadien-1-yl)[(1,2,3,4,5,6,-η)-(1-methylethyl) benzene]-, hexafluorophosphate(1-) as a photoinitiator in adhesives for use in food-contact articles.

In the filing notice, FDA utilized the Chemical Abstract Service nomenclature to identify the additive. However, in the final rule, the common name (η^5-cyclopentadienyl) (η^6-isopropylbenzene)iron(II) hexafluorophosphate, is used because the structure of the food additive is more readily comprehended from this name.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe, and that § 175.105 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 14, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

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, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding a new entry to the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * *	* * *
(η^5-Cyclopentadienyl)-(η^6-isopropylbenzene)iron(II) hexafluorophosphate (CAS Reg. No. 32760–80–8).	For use only as a photoinitiator.
* * *	* * *

Dated: August 31, 1994.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–22648 Filed 9–13–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 813, 882, 887, and 982

[Docket No. R–94–1628; FR–3727–C–02]

RIN 2577–AB47

Section 8 Certificate and Voucher Programs Conforming Rule: Admissions—Correction Concerning Effective Date

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

ACTION: Final rule; Technical correction.

SUMMARY: On July 18, 1994 (59 FR 36662), HUD published in the **Federal Register** a final rule for the Section 8 Certificate and Voucher Programs. The purpose of this document is to correct the "Effective Dates" section of the rule to include § 982.210(c)(4)(ii) as another section of the rule that will not be effective until January 18, 1995. The remainder of the "Effective Dates" section remains unchanged.

EFFECTIVE DATE: Except for §§ 982.209(b) and 982.210(c)(4)(ii), this rule is effective on October 18, 1994. Sections 982.209(b) and 982.210(c)(4)(ii) are effective January 18, 1995.

FOR FURTHER INFORMATION CONTACT: Madeline Hastings, Director, Rental Assistance Division, Room 4204, Telephone (202) 708–2841 (voice); (202) 708–0850 (TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On July 18, 1994 (59 FR 36662), HUD published in the **Federal Register** a final rule for the Section 8 Certificate and Voucher Programs. This final rule amended the requirements for admission of eligible families to receive tenant-based Section 8 rental assistance under the rental certificate program and the rental voucher program.

The purpose of this document is to correct the "Effective Dates" section of the rule to include § 982.210(c)(4)(ii) as another section of the rule that will not be effective until January 18, 1995. This section was inadvertently omitted when the rule was published on July 18, 1994. The remainder of the "Effective Dates" section remains unchanged.

Accordingly, the "Effective Dates" section in FR Doc 94–16887, a final rule published in the **Federal Register** on July 18, 1994 (59 FR 36662), is corrected to read as follows:

EFFECTIVE DATES: Except for §§ 982.209(b) and 982.210(c)(4)(ii), this rule is effective on October 18, 1994. Sections 982.209(b) and 982.210(c)(4)(ii) are effective January 18, 1995.

Dated: September 7, 1994.

Brenda Gladden,

Assistant General Counsel for Regulations (Acting).

[FR Doc. 94–22637 Filed 9–13–94; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 94–94]

Exemption of System of Records Under the Privacy Act

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice, FBI, revises § 16.96 of Title 28 of the Code of Federal Regulations to exempt a Privacy Act system of records from subsections 5 U.S.C. 552a (c)(3), (c)(4), (d), (e)(1), (2), and (3), (e)(4) (G) and (H), (e)(5), (e)(8), (f) and (g) of the Privacy Act. The system of records is the FBI Counterdrug Information Indices System. Information in the system consists of automated indices related to the law enforcement activities and responsibilities of the FBI regarding drug law enforcement. These exemptions are necessary to avoid interference with the law enforcement functions and responsibilities of the FBI. Reasons for the exemptions are set forth in the text below.

EFFECTIVE DATE: September 14, 1994.

FOR FURTHER INFORMATION CONTACT: Patricia E. Neely, (202) 616–0178.

SUPPLEMENTARY INFORMATION: This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby stated that the order will not have a "significant economic impact on a substantial number of small entities."

List of Subjects in Part 16

Administrative Practices and Procedure, Courts, Freedom of Information Act, Government in the Sunshine Act, and Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, 28 CFR Part 16 is amended as set forth below.

Dated: August 29, 1994.

Stephen R. Colgate,

Assistant Attorney General for Administration.

1. The authority for Part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717, 9701.

2. Title 28 CFR, Section 16.96 is amended by adding paragraphs (l) and (m) as set forth below.

§ 16.96 Exemption of Federal Bureau of Investigation (FBI)—Limited Access

* * * * *

(l) The following system of records is exempt from 5 U.S.C. 552a (c)(3), (c)(4), (d), (e) (1), (2), and (3), (e)(4) (G) and (H), (e)(5), (e)(8), (f) and (g).

(1) FBI Counterdrug Information Indices System (CIIS) (JUSTICE/FBI—016)

(m) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a (j)(2). Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal