3. The Director of Air Traffic Service is authorized to—

(a) Make revisions and additions to the operations schedule established by an air carrier pursuant to paragraph 1 of this appendix to the extent the controller work force at the air traffic control facilities involved can accommodate those changes.

(b) Establish schedule reductions for any hour not specified in paragraph 1 of this appendix (nonpeak-operation hours) if excessive flights are rescheduled for any of those hours.

(c) Approve new or additional service into a designated airport. A new air carrier that had its application for an operating certificate on file with the Civil Aeronautics Board prior to August 3, 1981, will receive approval for some operations. Adjustments to other air carrier operations schedules may be made by the Director of Air Traffic Service to accommodate new air carriers. Other new entrants may be authorized to operate at the designated airports only if the then current capacity permits.

(Secs. 307 (a) and (c), 313(a), and 601(a), Federal Aviation Act of 1958, as amended (49 U.S.C. 1348 (a) and (c), 1354(a), and 1421(a)); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c))

Note.—The FAA has determined that this rule is an emergency regulation under the provisions of Section 8 of Executive Order 12291 and the Department's Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). It is impracticable for the FAA to follow the procedures of Executive Order 12291 applicable to regulations not issued in response to emergency situations because the safety and efficiency of the national air transportation system require immediate implementation of the rule. Voluntary compliance with this regulation is expected. If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the persons identified under the caption "For Further Information Contact."

This is a final rule of the Administrator issued in accordance with the Federal Aviation Act of 1958, as amended. Thus, in accordance with section 1006 of the Act (49 U.S.C. 1486), it is subject to review only by the courts of appeals of the United States or the United States Court of Appeals for the District of Columbia.

Issued in Washington, D.C. on September 2, 1981.

J. Lynn Helms,

Administrator.

[FR Doc. 81-26155 Filed 9-3-81; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 135

[Docket No. 78P-0374]

Frozen Desserts; Ice Cream, Frozen Custard, Ice Milk, and Sherbet; Amendment to the Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standards of identity for ice cream and frozen custard, ice milk, and sherbet to permit, in addition to sweet whey that is now permitted, the use of acid whey and modified whey products made from sweet and acid wheys as a source of whey solids. These whey sources may be used singly or in combination as long as the total whey solids do not exceed the maximum limits for whey solids allowed in the applicable frozen dessert standard. The maximum limits for total whey solids in these standardized frozen desserts remain unchanged.

DATES: Effective July 1, 1983, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

Voluntary compliance: November 3, 1981.

Objections by: October 5, 1981.

ADDRESS: Written objections to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 17, 1979 (44 FR 48265), FDA published a proposal to amend the standards of identity for ice cream and frozen custard, and sherbet (21 CFR 135.110 and 135.140, respectively) and, by cross-reference, the standard of identity for ice milk (21 CFR 135.120). FDA published the proposal in response to a citizen petition filed by the International Association of Ice Cream Manufacturers (IAICM), the Whey Products Institute (WPI), and Foremost Foods Co. The proposed amendment would permit the use of sweet whey, acid whey, and modified whey products made from sweet and acid wheys as a source of whey solids as long as the total amount of whey solids used does not exceed current limits in the frozen dessert standards.

FDA concludes that the proposed provisions for the use of whey and modified whey products are reasonable and is so providing in §§ 135.110(b) and 135.140(b) of the final regulations set forth below.

Eleven letters, each containing one or more comments, were received in response to the proposal. The issues raised in the comments and the agency's responses are as follows:

1. One comment objected to the proposal because it would allow more synthetic additives and less natural food.

FDA disagrees. The current ice cream regulation provides for the use of sweet whey (derived from the manufacture of sweet-curd-type cheeses) in an amount not to exceed 25 percent by weight of the total nonfat milk solids content of the finished product. The proposal to amend the regulation retains the 25-percent maximum usage level but would allow the optional use of acid whey (derived from the manufacture of acid-curd-type cheeses) and modified forms of sweet and acid wheys as a source of whey solids. Because both types of whey are derived from cheeses, the change in the standard does not allow the use of more synthetic additives.

2. One comment considered the terminology for "modified whey" in the preamble to the frozen dessert proposal to be inconsistent with the common or usual name proposed in the GRAS affirmation document published in the **Federal Register** of June 22, 1979 (44 FR 36416). In addition, one comment asserted that the absence of uniform common or usual names for acid whey and modified whey products would create unnecessarily confusing labeling requirements.

FDA disagrees. The GRAS affirmation proposal would establish common or usual names for acid whey and modified whey products, and these are the names to be used. The terminology for "modified whey" published in the preamble to the frozen dessert proposal was submitted by the International Association of Ice Cream Manufacturers as part of its petition. It was included in the preamble only as background

information and was not part of the proposal. It is not a part of the final regulation set forth below. Therefore, the standards of identity for frozen desserts require that when whey or modified whey products are used, they must be declared on the label by the common or usual name established by the final GRAS affirmation regulation, published elsewhere in this issue of the Federal Register.

The sole purpose of making reference in these standards to whey and modified whey products determined to be GRAS for use in frozen desserts, rather than listing each such ingredient by name, is to permit the use of whey or any ingredient derived from whey that is either affirmed as GRAS for such use in the final GRAS affirmation regulation or that may be affirmed as GRAS for such use by FDA at some future date. Thus, this amendment makes unnecessary further amendments to the frozen dessert standards for this purpose.

3. One comment questioned the nutritional equivalency concept as a valid basis for the use of acid whey and modified whey products.

FDA advises that, although nutritional equivalency is important, the primary basis for this amendment is to allow the use of additional suitable ingredients in frozen desserts. Further, independent studies and FDA's own nutrient comparison investigations demonstrate that the limited use of whey and modified whey products, as provided for in the final regulations, will not result in a measurable reduction in the nutrient value of frozen desserts. Copies of the reports on these studies and on FDA's investigations are on file with the Dockets Management Branch, Food and Drug Administration.

4. One comment recommended that 21 CFR 101.4(b)(7) be amended to read: "Whey, concentrated whey, reconstituted whey, dry whey, reduced lactose whey, reduced minerals whey, and whey protein concentrate may be declared as 'whey' ".

FDA believes that this recommendation goes beyond the scope of the proposal. Any interested person who believes that 21 CFR 101.4(b)(7) should be amended to permit modified whey products to be declared as "whey" may submit a petition presenting reasonable grounds in support of this proposed amendment.

5. One comment asked whether the phrase "determined to be generally recognized as safe (GRAS)" refers to the other optional dairy ingredients listed in the standard as well as "modified wheys" or "whey and modified wheys".

FDA advises that the "other optional dairy ingredients" are already provided for in the frozen desserts standards. Any reconsideration of their status as ingredients in frozen desserts is not within the scope of these amendments to the frozen dessert standards.

6. One comment suggested that the frozen dessert standards would be revised to permit the use of any safe and suitable wheys or whey fractions so that the development of new kinds of whey fractions can continue. The comment suggested that, if this revision is not possible, FDA should at least permit the use of whey products determined independently by manufacturers to be GRAS, as well as those wheys and modified whey products listed in the GRAS affirmation proposal of June 22, 1979. The comment also suggested that, for clarity, the specific names of the wheys and modified whey products affirmed as GRAS should be listed in the revised standards.

FDA believes that it cannot assure that a measurable reduction in nutrient value of frozen desserts will not occur if it permits the use of any safe and suitable wheys and modified whey products or provides for the use of whey products determined independently to be GRAS. FDA recognizes that 21 CFR 170.30 states that general recognition of safety may be based on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to foods, and that such language would permit an independent evaluation of the GRAS status of such ingredients. However, the fact that a substance is GRAS only reflects its safety and not its nutritional value. The intent of these amendments to the frozen dessert standards is to permit the use in frozen desserts of those additional modified whey products that are not merely GRAS but that will not cause a measurable reduction in the nutrient value. FDA has determined that acid whey and the modified whey products that it has affirmed as GRAS will not cause such a reduction, and therefore, it is permitting their use.

FDA agrees that a clarification of the kinds of modified whey products permitted should be included in the standards. Thus, the phrase "* * * and whey and modified wheys determined to be generally recognized as safe (GRAS)" is changed to read "* * * 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."

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 135 is amended as follows:

PART 135—FROZEN DESSERTS

1. In § 135.110 by revising paragraph (b) to read as follows:

§ 135.110 Ice cream and frozen custard.

* * * * *

(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 has been concentrated and from which part of the lactose has been removed by crystallization, 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.

* * * * *

2. In § 135.140 by revising paragraph (b) to read as follows:

§ 135.140 Sherbet.

* * * * *

(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, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, 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 has been concentrated and from which part of the lactose has been removed by crystallization, 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 person who will be adversely affected by the foregoing amendments may at any time on or before October 5, 1981, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each number objection shall specify with particularity the provision of the regulation to which objection is made. 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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin November 3, 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply. FDA will publish in the **Federal Register** notice of the filing of objections, or that no objections were filed.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: August 11, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-25544 Filed 9-3-81; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 184

[Docket No. 78N-0369]

GRAS Status of Whey, Whey Products and Hydrogen Peroxide

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that whey and certain modified whey products are generally recognized as safe (GRAS) as direct human food ingredients, and that hydrogen peroxide is GRAS for use as an antimicrobial agent in cheesemaking and whey processing. This action is taken in response to petitions requesting such affirmations.

EFFECTIVE DATE: September 4, 1981. Compliance with the labeling provisions of this final regulation may begin immediately. Labeling of all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983 shall comply with these provisions.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: Under the procedures established in § 170.35 (21 CFR 170.35), Foremost-McKesson, Inc., Crocker Plaza, One Post St., San Francisco, CA 94104, submitted a petition (GRASP 3G0011) requesting affirmation that delactosed whey, demineralized whey, and delactosed-demineralized whey are GRAS for use in foods, and that hydrogen peroxide is GRAS for use as an antimicrobial agent in the processing of whey. FDA published a notice of the filing of this petition in the **Federal Register** of March 7, 1973 (38 FR 6215). Seven comments were received in response to this notice. A subsequent petition by the Whey Products Institute, to establish common or usual names for whey and modified whey products, made it evident that additional safety information from other whey processors was needed to determine the proper regulatory status of these products before common or usual names could be adopted for the ingredients. In the **Federal Register** of December 17, 1975 (40 FR 58485), FDA requested submission of additional GRAS affirmation petitions and safety data on modified whey products produced by other processors. As stated in that notice, the agency intended to make a class determination whether sufficient safety data were available to affirm the GRAS status of these products and to establish common or usual names through GRAS regulations if sufficient data were available.

In response to the above notice, FDA received nine additional petitions. FDA published notice of the filing of these petitions in the **Federal Register** of June 22, 1979 (44 FR 36416). No comments were received in response to the notice. The petitioners and the GRAS numbers assigned to their petitions are as follows:

GRAS Petition

Number	Petitioner
6G0063	Frank Thomas, Greenwood, WI 54437.
6G0065	Dean Foods Co., 1126 Kilburn Ave., Rockford, IL 61101.
6G0068	Stauffer Chemical Co., Westport, CT 06880.
6G0070	Western General Dairies, Inc., 195 West 7200 South, Midvale, UT 84047.
6G0071	Purity Cheese Co., P.O. Box 27, Mayville, WI 53050.
6G0073	Borden, Inc., 180 E. Broad St., Columbus, OH 43215.
6G0075	Land O'Lakes, Inc., P.O. Box 116, Minneapolis, MN 55440.
6G0076	Krafico Corp., 135 S. LaSalle St., Chicago, IL 60603.
6G0078	Tetroid Co., Inc., Hamilton, NY 13346.

A copy of each petition was made available for public examination and comment at the Dockets Management Branch (formerly the Hearing Clerk's office), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

In response to the petitions, the agency published a proposed regulation in the **Federal Register** of June 22, 1979

(44 FR 36416). The proposed regulation listed common or usual names and definitions for the whey products, descriptions of the manufacturing processes, approximate compositions, methods of analyses, specifications, and indicated good manufacturing practice (GMP) uses and levels of use in foods for the ingredients. The publication of regulations proposing affirmation of GRAS status for hydrogen peroxide and for whey and modified whey products followed a determination by FDA, based on the data and information that had been submitted, that the proposed uses of these ingredients were GRAS.

FDA received no comments that questioned the safety of the whey products or the hydrogen peroxide. However, a prepublication manuscript of an animal study by Ito, Watanabe, and Niato suggested that hydrogen peroxide may cause cancer in the duodenum of mice. (An official of the Embassy of Japan in Washington, DC, provided FDA with the manuscript.) The Japanese study was a lifetime carcinogenicity study in which hydrogen peroxide in drinking water at 0.1 percent and 0.4 percent was administered to C57B1/6J mice for 108 weeks.

The agency has considered the available safety data on hydrogen peroxide, including the Japanese study and subsequent clarification obtained from the authors. FDA concludes after this review that there is not sufficient evidence from the Japanese study and elsewhere to conclude that hydrogen peroxide is a duodenal carcinogen. The agency made the same determination in adopting the regulation that permits the use of hydrogen peroxide as a sterilizing agent for polyethylene used in contact with food (21 CFR 178.1005) (46 FR 2341; January 9, 1981). The manuscripts of the Japanese study and memoranda of FDA's Cancer Assessment Committee meetings, along with other articles referenced, are on public file under the docket number for this document at the Dockets Management Branch (address above), and may be seen from 9 a.m. to 4 p.m., Monday through Friday.

The agency has also evaluated whether any residual hydrogen peroxide may occur in cheese and whey products from use in processing. Hydrogen peroxide rapidly decomposes to oxygen and water when used as a bleaching agent or, as in cheesemaking and whey processing, as an antimicrobial agent. However, because of analytical limitations for detecting residual hydrogen peroxide in food (the detection limit is approximately 10 parts per million (ppm)), the degree of decomposition of hydrogen peroxide at levels less than 10 ppm is unknown. It is well known, however, that hydrogen peroxide is very reactive, and that many substances either promote or catalyze its decomposition. Either added or naturally occurring catalase and peroxidase enzymes cause an extremely rapid decomposition of hydrogen peroxide, while many metal ions and organic substances cause much slower decomposition. Increases in temperature and an increase in pH also contribute to more rapid rates of decomposition of this substance.

In evaluating potential residual levels below 10 ppm of hydrogen peroxide in food, it is relevant that Amin and Olson (Ref. 1) have shown that 500 ppm of hydrogen peroxide underwent negligible decomposition after 2 hours in distilled water at 37.8° C (100° F). Under similar conditions, breakdown amounted to 5 percent in standard phosphate buffer, 30.3 percent in sterilized reconstituted nonfat dry milk, 37.2 percent in sterilized homogenized whole milk, and 66.2 percent in raw milk in the same time period. The significantly enhanced rate of decomposition observed in raw whole milk was attributed to the naturally occurring presence of catalase and peroxidase enzymes in raw milk. Dempsey, et al. (Ref. 2) also found that the half-life for the decomposition of hydrogen peroxide in sterilized reconstituted skim milk was about 2 hours at 25° C (77° F).

During the preparation of demineralized whey, delactosed whey, and demineralized-delactosed whey, hydrogen peroxide is added at a maximum level of 400 ppm, prior to demineralization and lactose crystallization, to prevent bacterial growth that is likely to occur under the conditions of elevated temperatures (29.4° to 48.9° C (85° to 120° F)) employed during these steps. Following whey fractionation, catalase is then added to eliminate the hydrogen peroxide. Analytical measurements following catalase treatment are unable to detect hydrogen peroxide residues at a level of 10 ppm in the liquid-fractionated whey.

In a similar use for cheesemaking, hydrogen peroxide is added to milk at a maximum level of 500 ppm to reduce the number of bacteria in the milk at the beginning of the cheesemaking process. The hydrogen peroxide decomposes rapidly, and catalase enzymes are added to destroy any residual hydrogen peroxide prior to the addition of cheesemaking enzymes. This use of hydrogen peroxide has been practiced since at least the early 1950's without any known detrimental effect or any observed residual levels of hydrogen peroxide in the cheese or whey byproduct.

Based on experimental data in the cited articles (Refs. 1 and 2), it appears that nearly all added hydrogen peroxide is destroyed in cheesemaking and whey fractionation before the addition of catalase, and that the addition of catalase enzyme virtually assures its destruction. As a result, the agency concludes that the projected level of hydrogen peroxide in either the processed whey or in the subject cheeses, although not analytically detectable, approaches the intracellular level reported to be in the liver of rats (and supposedly humans as well) and is so low that the two uses of hydrogen peroxide in cheesemaking and whey manufacture can be affirmed as GRAS.

Of the 45 comments on the proposal, 35 were from individual firms, 6 were from associations, 2 were from attorneys, and 2 were from other agencies in the Federal government. A summary of the comments and the agency's responses follow:

1. Two comments concerned the use of hydrogen peroxide in the processing of cheese and whey. The U.S. Department of Agriculture (USDA) stressed the need for the final regulation to permit the use of hydrogen peroxide according to good manufacturing practices and not to serve as a substitute for them. The other comment objected to the proposed use of hydrogen peroxide "in the holding tank before processing," because this phrase suggested that the hydrogen peroxide may be added only to the stored whey before processing and not during its fractionation.

FDA agrees with USDA's comment that all uses of hydrogen peroxide must be limited to the minimum amount necessary to produce the intended technical effects and cannot be substituted for other good manufacturing practices, including sanitary practices. The use levels of hydrogen peroxide affirmed as GRAS in this regulation are the maximum levels of good manufacturing practice (GMP) use reported to the agency and should not be interpreted as encouragement to use these levels if it is not necessary to do so. Section 184.1 (21 CFR 184.1) of the GRAS affirmation regulations clearly states this policy.

In response to the second comment, FDA has amended the final regulation to permit the continued existence of hydrogen peroxide in whey during fractionation. Although hydrogen peroxide is usually added to the processing tank, it need not be removed, with catalase, before fractionation.

2. Twenty comments took issue with the indicated GMP technical effects, food categories, and levels of use in the proposal for these whey and whey products. New technical effects and an expansion of use to include virtually all food categories, at various levels, were requested for whey, reduced lactose whey, reduced minerals whey, and whey protein concentrate. The comments stated further that the proposed regulation did not establish any safety basis to limit use of these ingredients to present uses. In addition, a comment argued that these limits would serve only to prevent developing technology aimed at increasing the use of these highly nutritious and, at present, largely wasted food materials. Another comment pointed out that it would be inconsistent to establish the same GMP levels for use in food of two substances that may vary widely in their composition. For example, one whey protein concentrate may contain 30 percent protein, while another contains 80 percent protein. It was also argued that the levels of use of these whey and whey products are self-limiting, because of the taste factor. Finally, comments expressed concern the GMP levels of use in these GRAS regulations would exceed those levels permitted in the food standards.

After full consideration of these comments, FDA has concluded that designation of GMP technical effects, food categories, and levels of use should not be included in this final regulation. These matters were included in the proposal to list the technical effects, food categories, and levels of use that were presented to FDA as part of the several petitions it received and not to limit potential future use of these substances. There is no known safety hazard with present or potential food uses of these ingredients, and, therefore, there is no basis to establish or to imply that these ingredients need to be limited for future food use on the basis of safety. The final regulations have been amended to state that whey, reduced lactose whey, reduced minerals whey, and whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

Removal of the listing of the food categories and subcategories from the final regulation is also responsive to the concerns raised by several comments over the possibility of conflict between these GRAS regulations and certain food standards. The agency emphasizes, however, that the limitations established in the food standards take precedence over any use suggested by the GRAS regulations. Removal of food standard limitations requires submission of a petition and FDA's approval of changes in those standards.

3. Four comments expressed concern that the intended labeling provisions for whey, reduced lactose whey, reduced minerals whey, and whey protein concentrate in the proposed regulation were not clear for bulk packaging and did not address packaging for finished food products. Six additional comments requested that § 101.4(b)(7) (21 CFR 101.4(b)(7)) be amended to permit all of these ingredients to be labeled as "whey" in finished food products, while three other comments favored amending § 101.4(b)(7) to permit reduced lactose whey, reduced minerals whey, and whey protein concentrate to be labeled "modified whey." Other comments stated that requirements for bulk labeling in these whey regulations were unnecessary and were provided by § 184.1(f), that these whey and whey products were exempted from bulk labeling under § 101.9(h)(8) (21 CFR 101.9(h)(8)), and that the need for labeling was eliminated by § 102.5(b)(1) (21 CFR 102.5(b)(1)), which deals with nonstandardized foods.

In the proposed regulation, FDA did not address the labeling requirements for whey and whey products on finished food labels because it was unnecessary to do so. Section 101.4(b)(7) clearly permits the use of the name "whey" on finished food labels when whey, concentrated whey, reconstituted whey, and dried whey are used as source ingredients. Therefore, this final regulation does not affect the finished food labeling for whey, concentrated whey, reconstituted whey, and dried whey. This final regulation does however, establish names, definitions, approximate compositions and specifications for identifying these ingredients except for reconstituted whey, when supplied to food manufacturers. Reconstituted whey is not addressed in this regulation because it is the name of a product produced by adding water to dry whey. Thus, the resultant product is equivalent to whey or concentrated whey, depending on the amount of added water. Section 184.1(f) also applies to bulk labeling for these ingredients when sold to food manufacturers. The regulation for whey has been modified to clarify FDA's intent.

Adoption in the proposed regulation of specific names and descriptions for reduced lactose whey, reduced minerals whey, and whey protein concentrate was intended to establish common or usual names for these ingredients. These names may be used on finished food labels and on intermediate mixes sold to food manufacturers. Because § 101.4(a) permits the use of common or usual names for finished food labels, it is not necessary to adopt these names in § 101.4(b)(7). However, the proposed regulation did not make it clear that finished food products would need to declare only reduced lactose whey, reduced minerals whey, or whey protein concentrate and would not need to include the more descriptive names required for intermediate mix labeling, i.e., reduced lactose whey (55 percent lactose). This final regulation has been modified to clarify FDA's intent.

The agency has also considered whether it should amend Part 101 (21 CFR Part 101) to permit the use of names such as "modified whey" or "whey products" for ingredient listing of reduced lactose whey, reduced minerals whey, and whey protein concentrate on finished food product labels, and whether it should expand the use of the term "whey" for this purpose. FDA has decided that both of these actions are inappropriate because the more descriptive names of "reduced lactose whey," reduced minerals whey," and "whey protein concentrate" better identify these ingredients. Therefore, FDA has not made any substantive change in the final regulation to respond to these comments.

4. Eleven comments expressed concern about the proposed definition of whey. Specific concern was expressed about the limited definition of whey as "obtained from cheesemaking." One comment argued that this limited definition would have the effect of eliminating casein whey from food use. Many of these comments expressed concern about the narrow definitions of sweet whey and acid whey. In the proposed regulation, these types of whey were differentiated only on the basis of the amount of lactose converted to lactic acid. The comments observed that this differentiation does not consider wheys obtained from production of such cheese products as cottage cheese, that are made by directly acidifying with acids and without relying on lactic acid to contribute significantly to the acidity. Also, there was general disagreement with the propqsed regulation's intent to define sweet whey and acid whey within the general definition for whey. In addition, three comments argued that intermediate pH wheys are obtained from cheesemaking process, and that it was therefore necessary to define a third type of whey if the proposed approach is adopted.

After considering these comments, the agency concludes that if information were provided to the food processor on the percent titratable acidity in the whey, it would not be necessary for this regulation to define sweet whey or acid whey. However, to provide that whey may be either sweet or acid, without specific identification of the titratable acidity of either type of whey, requires that at least one of these types of whey be defined in the general definition for whey. The proposed definition for sweet whey therefore has been retained in the final regulation. However, FDA also has amended the regulation to permit whey suppliers to identify whey, concentrated whey, and dried whey as sweet products or as acid products or to declare the percent titratable acidity on the label of the intermediate mix.

Finally, FDA has considered whether it is desirable to identify a third type of whey within this definition (intermediate pH whey). The agency has concluded that such a definition could be confusing and possibly misleading. In addition, because this type of whey falls in the titratable acidity range of acid whey, its identity is disclosed by the name acid whey or by the titratable acidity level.

Even with these changes in the final regulation, food manufacturers are free to require that whey suppliers provide detailed information on the acidity of their products, as well as other compositional data, if this information is needed.

The proposed definition of whey included only whey from cheesemaking because no petitions were submitted on casein whey. As a result, the final regulation does not deal with casein whey. FDA approval of this substance will require the submission of a separate GRAS affirmation or food additive petition under the procedures outlined in § 170.35 or § 171.1 (21 CFR 171.1). FDA has retained the original reference to cheesemaking in the final regulation.

FDA has changed the final regulation to eliminate the reference to substantial lactic acid acidity as part of the definition for acid whey. The regulation states that acid whey may be obtained from direct acidification cheesemaking processes.

5. Sixteen comments objected to some aspect of the identified names for the whey products or their definitions. Most objected to the use of the word "dried" as part of the title for all whey products, because these whey products are commercially available as fluid, concentrated, and dry products. Other comments expressed a preference for the term "condensed," rather than "concentrated," for those wheys from which some moisture has been removed. In addition, the comments stated that the terms "dry" and "condensed" would be most appropriate because these terms have been used to describe similar milk products intended for human consumption.

The words "dried" and "concentrated" were used in the proposed regulations for whey and whey products because these words are used in § 101.4(b)(7) to identify the forms of whey that can be listed as "whey" on a package label. The agency agrees that "dry" and "dried" are synonymous as they relate to both whey and milk products, and it has modified the regulation to provide for the use of "dry" or "dried" as the descriptor. Thus, the industry can continue its present practice of identifying whey intended for human consumption as "dry whey" and whey intended for animal uses as "dried whey." However, the words "concentrated" and "condensed" do not relate to whey and milk products that are similar. In the milk standards, the term "condensed" is associated with a product to which a nutritive carbohydrate sweetener is added, and from which some water is removed. However, "concentrated milk" is a term for a product from which some water is removed but to which no sweetener is added. Only the latter product is analogous to concentrated whey. Thus, the term "concentrated whey" has been established and has been retained as the descriptive name for this form of whey.

6. Some comments on the proposed regulation objected to the use of the term "selective removal" to describe removal of lactose and minerals to produce reduced lactose whey and reduced minerals whey. The comments emphasized that in the process of producing these whey products, it is impossible to prevent the removal of components other than the one named. In addition, the comments insisted that the requirement for the removal of a stated percentage of lactose or of minerals to produce these reduced wheys is both needless and unenforceable, because of the variable ingredient percentages in the starting wheys. Furthermore, the comments argued that the regulation should rely on the label statement of the percentage of the ingredients in the final product.

FDA is replacing the term "selective removal" with the term "removal". This change will make it clear that components other than the one indicated in the title may also be removed in the manufacture of reduced lactose whey and reduced minerals whey. The final regulation has also been modified to eliminate reference to the amounts of lactose or minerals expected to be removed from the starting whey and to make it clear that the final product compositions are the only relevant limitations for these products.

7. Nine comments addressed the proposed methods of preparation for reduced lactose whey, reduced minerals whey, and whey protein concentrate. Some stated that the proposed regulation failed to list all the methods used to prepare the modified wheys, such as reverse osmosis, ultrafiltration, and other membrane technology. The Comments expressed concern that the listed methods were the only ones that would be permitted. Other comments stated that descriptions of the methods for preparing the modified wheys should be shorter and more general or not included in the regulation at all. One comment stated that the methods of preparation had been described in the petition; that they are common knowledge throughout the industry; and that their inclusion in the regulation would inhibit the development of more efficient acceptable practices.

FDA realizes that to describe all manufacturing processes in detail would result in a regulation that is unnecessarily specific. Also, the agency did not believe that discussions of the methods are needed in the regulation because a number of the methods were already discussed in detail in the preamble to the proposed regulation. The agency does not intend to limit the processing methods that may be used. Furthermore, the agency has no objection to the use of newly developed physical separation techniques, if there are no new toxicants introduced as a result of use of these techniques, and if these techniques do not result in a concentration of natural toxicants in whey products. FDA believes that such results can be avoided by the use of good manufacturing practices and by the establishment of specifications for heavy metals. Therefore, the agency has used the term "prepared by physical separation techniques *such as* precipitation, filtration, or dialysis" (emphasis added) to describe briefly the methodologies that have been reviewed and at the same time to avoid eliminating other acceptable methods.

8. Thirteen comments objected to the methods proposed to determine the levels of fat, protein, ash, lactose, and moisture in whey and whey products. The comments were concerned that the proposed Association of Official Analytical Chemists (AOAC) methods were for cereal products and liquid milk.

The comments suggested use of alternative AOAC methods, except those for fat and moisture determinations. The methods suggested for fat determination were the same as those in the proposal, and the methods for moisture analysis was one published in a USDA directive. The Comments stated that these methods were used by industry in milk and whey analyses.

The agency has examined the methodology recommended in the proposed regulation and the alternative methods proposed by these comments. There are only two differences between these methods: the type of sample and the size of the sample. FDA's proposed method, the AOAC method, analyzes a liquid sample weighing 5 grams. The industry uses a dried sample weighing 1 gram. Although the latter sample is smaller, the analysis is done on a larger amount of solids, because liquid milk contains about 13 percent solids. Additionally, the description of these products permits both liquid and solid forms. As a result, the agency has adopted both AOAC methods for analysis of ash, protein, and lactose for appropriate forms of the product. However, this final rule does not adopt the method for moisture analysis described in the USDA directive. Although the USDA method may be an acceptable screening method, § 2.19 (21 CFR 2.19) requires that FDA use AOAC methods of analysis, when available, for enforcement purposes. Therefore, the agency has replaced the proposed AOAC method for determining moisture in cereals with another more applicable AOAC method for determining moisture in milk.

9. Five comments objected to the proposed percentage increments for use in the label declarations on bulk packages of whey and whey products for protein (5 percent), lactose (5 percent), and minerals (2 percent) as being impractical, unnecessary, or representing too great an economic variation. These comments preferred 2 percent increments for protein and lactose and 1 percent increments for minerals, because they contended that food processors needed more accurate information on the component levels than the proposed increments would provide.

The agency had proposed the indicated increments for stating the percentages of the components on the labels for whey products to enable the whey processor to meet the bulk lable declarations regardless of the slight variability that may result from processing methodology. FDA believed that the large proposed increments would enable the whey processor to standardize its procedures and still meet the desired percentage of the appropriate component in the whey products. FDA did not anticipate the five comments' desire for more exact statements of percentages. It is the agency's opinion, however, that insistence on label declarations using smaller increments might cause compliance problems for smaller firms. Therefore, the agency has resolved the matter by permitting a choice of using either the proposed increments on the lable declarations or smaller incremental declarations. If smaller increments are used, an analysis, as described by the regulations, must be supplied to the food manufacturer. FDA has changed the regulations to permit this choice.

10. Eight comments requested changes in the proposed component ranges for the various whey products. Several comments expressed concern that the percentage ranges did not resemble those found in existing whey products. One comment suggested that the ranges be adjusted to relate to other whey products. For example, because whey protein concentrate contains a minimum of 25 percent protein, the percent protein level in the reduced lactose or reduced minerals whey should be as high as 24 percent, which is easily attainable in a reduced lactose whey. Similarly, whey and whey products could have a range of fat from 0.2 to 4.0 percent, depending on the milk source used to make the cheese.

The agency agrees that the percentage ranges stated in the comments are consistent with those found in current products and has modified the percentage ranges for the various components of whey and whey products to conform to those ranges that were suggested in the comments.

11. Three comments objected to the agency's failure to include in the proposed regulation two proposed modified whey products, whey minerals concentrate and whey lactose concentrate. Whey minerals concentrate is produced by the removal of high percentages of protein and lactose. Whey lactose concentrate is produced by the removal of high percentages of protein and minerals. The comments stated that these products were mentioned in the preamble to the proposed regulation by use of the term "liquid permeate".

FDA did not consider these two whey products in the proposed regulation because data submitted to the agency suggested that the permeate byproducts of reduced lactose whey, reduced minerals whey, and whey protein concentrate were processed further to remove lactose, and then discarded. The agency was informed by one petitioner that potential permeate uses were clearly not as human food but as bacterial media ingredients and cattle mineral sources. However, the agency believes that these two products are suitable subjects for food additive or GRAS affirmation petitions, if any interested person wishes approval of these products for human uses.

12. One comment requested information on the status of a "reduced" lactose whey, in which lactose reduction involved the enzymatic or other hydrolysis of lactose in whey to glucose and galactose.

FDA's intent in this review has been to evaluate the safety of physical separation methods for producing whey products. The agency has not reviewed the safety or established specifications for modified whey products produced by chemical hydrolysis or enzymatic processes and cannot comment on the applicability of these methods without more information. Important information required to evaluate these processes would include the chemical system used to produce hydrolysis, the bacteriological source of the enzymes, and the specifications for the finished reduced lactose whey. The agency, therefore, recommends the submission of a food additive or GRAS affirmation petition containing such information.

13. Four comments expressed concern about the proposed classification of their currently marketed products, which are sold as denatured albumin, concentrated reduced minerals whey, concentrated reduced lactose whey, and concentrated whey protein concentrate.

In the proposed regulation, the agency discussed the review of precipitation procedures to isolate whey protein. With the use of heat, whey protein is denatured and precipitates out of solution. It is then removed by the use of a centrifugal decanter and filtration. This method is capable of producing a whey protein concentrate with a level of protein greater than 90 percent on a dry basis.

When FDA prepared the proposal, it did not include concentrated reduced lactose whey, concentrated reduced minerals whey, and concentrated whey protein concentrate because FDA believed that the dried form was the article of commerce and did not know that the liquid and concentrated forms of the whey products also were articles of commerce. However, the agency has corrected this error in the final regulation and believes that these

products will fit into established whey product categories.

14. One comment requested information on whether FDA intends to permit unlimited pH adjustment for whey. A second comment requested that FDA permit pH adjustment for reduced minerals whey, reduced lactose whey, and whey protein concentrate.

The agency does not believe there is cause for concern in permitting the use of pH-adjusting agents in whey or whey products, because the use of these agents is self-limiting. The pH of whey is on the acidic side. The use of alkali to elevate the pH could result in precipitation of the protein if the isoelectric pH is reached. If the pH reaches the alkaline side, precipitation in the form of alkaline lactalbuminates will occur. Therefore, FDA expects that the pH-adjusting agents will be used only in accordance with good manufacturing practice for minor pH adjustment. The agency did not intend to imply in the proposed regulation, by mentioning pH adjustment for whey and not for whey products, that pH adjustment was not permitted for whey products. FDA has revised the final regulation for clarity.

15. One comment requested information about how a product composed of a mixture of whey protein concentrate and a soy protein concentrate should be labeled.

The agency does not believe that it should consider the labeling of this mixture in this final regulation. Nevertheless, FDA advises that a mixture of these two ingredients should be labeled in accordance with Part 101 and § 184.1(f). Section 184.1(f) indicates that the concentration of each of the two protein sources must be declared on the label of the intermediate mix.

16. Two comments stated that the issuance of GRAS regulations for whey, whey protein concentrate, reduced minerals whey, and reduced lactose whey were inappropriate because these products are foods rather than food ingredients, additives, or chemicals. The comments suggested that these definitions should be established through food standard regulations.

The agency believes that it is appropriate to regulate whey and whey products as food ingredients. Whey is a byproduct of cheesemaking, and whey protein concentrate, reduced minerals whey, and reduced lactose whey are manufactured substances made from whey. These substances are used as components in many food categories, including many standardized foods. In addition, as indicated by the petitions that have been submitted, the whey processors themselves consider these substances to be food ingredients.

Furthermore, it is incorrect to conclude that GRAS regulations are issued only for "chemicals". Although it is true that most GRAS ingredients are synthetically produced, there are also numerous naturally produced and refined natural ingredients included in GRAS regulations. Therefore, the agency concludes that GRAS regulations for these ingredients are appropriate.

References

1. Amin, V. M. and N. F. Olson, "Effect of Temperature on Stability of Hydrogen Peroxide in Milk," *Journal of Dairy Science*, 50(8): 1336–1338, 1967.

2. Dempsey, P. M., J. O'Leary, and S. Condon, "Polargraphic Assay of Hydrogen Peroxide Accumulation in Microbial Cultures," *Applied Microbiology*, 29: 170–174, 1975.

There is no requirement to prepare a Regulatory Impact Analysis under section 3(a) of Executive Order 12291, because this rule is not a major rule as defined in section 1(b) of Executive Order 12291. Because the effect of this rule will be to affirm the safety and maintain all known uses of the ingredients reviewed that are current practice within the food industry, this rule will not result in an annual effect on the economy of $100 million or more; will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. By adding new § 184.1366, to read as follows:

§ 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722–84–1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 146–147,[1] which is incorporated by reference.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level of use in milk during the cheesemaking process of 0.05 percent of the weight of the milk and of 0.04 percent of the weight of the whey during the processing of the whey. In either case, the residual hydrogen peroxide is removed by using a suitable catalase preparation.

(e) This regulation is issued before completion of general evaluation of the use of this ingredient in order to affirm as GRAS the specific use named.

2. By adding new § 184.1979, to read as follows:

§ 184.1979 Whey.

(a)(1) *Whey.* Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1*N* Hydrochloride per 100 grams. The acidity of whey, sweet or acid, may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(2) *Concentrated whey.* Concentrated whey is the liquid substance obtained by the partial removal of water from whey, while leaving all other

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

constituents in the same relative proportions as in whey.

(3) *Dry or dried whey.* Dry or dried whey is the dry substance obtained by the removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(b) The ingredients meet the following specifications:

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead), Not more than 10 parts per million (0.001 percent) as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512–513,[1] which is incorporated by reference.

(3) The whey must be derived from milk that has been pasteurized, or the whey and modified whey product must be subjected to pasteurization techniques or its equivalent before use in food.

(c) Whey, concentrated whey, and dry (dried) whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The label on the whey form sold to food manufacturers shall read as follows:

(1) For whey: "(Sweet or acid) whey" or "whey (——% titratable acidity).

(2) For concentrated whey: "Concentrated (sweet or acid) whey, ——% solids" or "Concentrated whey (——% titratable acidity), ——% solids".

(3) For dry (dried) whey: "Dry (dried) (sweet or acid) whey" or "dry (dried) whey, (——% titratable acidity)".

(e) Whey, concentrated whey, or dry (dried) whey in a finished food product shall be listed as "whey."

3. By adding new § 184.1979a, to read as follows:

§ 184.1979a Reduced lactose whey.

(a) Reduced lactose whey is the substance obtained by the removal of lactose from whey. The lactose content of the finished dry product shall not exceed 60 percent. Removal of the lactose is accomplished by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced lactose whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced lactose whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The reduced lactose whey meets the following specifications:

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 16 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 11 to 27 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, not more than 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the method prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512–513,[1] which is incorporated by reference.

(3) The reduced lactose whey shall be derived from milk that has been pasteurized, or the reduced lactose whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) Reduced lactose whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of lactose present on a dry product basis, i.e., "reduced lactose

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the office of the Federal Register, 1100 L St. NW, Washington, DC 20406.

whey (——% lactose)", shall be declared on the label of the package sold to food manufacturers. The percent of lactose may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of lactose in the product, or as a actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced lactose whey in a finished food product shall be listed as "reduced lactose whey."

4. By adding new § 184.1979b, to read as follows:

§ 184.1979b Reduced minerals whey.

(a) Reduced minerals whey is the substance obtained by the removal of a portion of the minerals from whey. The dry product shall not contain more than 7 percent ash. Reduced minerals whey is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced minerals whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced minerals whey may be adjusted by the additional of safe and suitable pH-adjusting ingredients.

(b) The reduced minerals whey meets the following specifications:

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists, 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 10 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, maximum 7 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, maximum 85 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solid."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512–513,[1] which is incorporated by reference.

(3) The reduced minerals whey shall be derived from milk that has been pasteurized, or the reduced minerals whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The reduced minerals whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of of minerals present on a dry product basis, i.e., "reduced minerals whey (——% minerals)", shall be declared on the label of the package sold to food manufacturers. The percent of minerals may be declared in 2-percent increments expressed as a multiple of 2, not greater than the actual percentage of minerals in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced minerals whey in a finished food product shall be listed as "reduced minerals whey".

5. By adding new § 184.1979c, to read as follows:

§ 184.1979c Whey protein concentrate.

(a) Whey protein concentrate is the substance obtained by the removal of sufficient nonprotein constituents from whey so that the finished dry product contains not less than 25 percent protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, whey protein concentrate can be used as a fluid, concentrate, or dry product form. The acidity of whey protein concentrate may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The whey protein concentrate meets the following specifications:

(1) The analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, minimum 25 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Officials Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 10 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 2 to 15 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, maximum 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—

Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512–513,[1] which is incorporated by reference.

(3) The whey protein concentrate shall be derived from milk that has been pasteurized, or the whey protein concentrate shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of protein present on a dry product basis, i.e., "whey protein concentrate (——% protein)", shall be declared on the label of the package sold to food manufacturers. The percent of protein may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of protein in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of whey protein concentrate in a finished food product shall be listed as "whey protein concentrate".

Effective date. This regulation shall be effective on September 4, 1981. Compliance with the labeling provisions of this final regulation may begin immediately. Labeling of all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall comply.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: August 11, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference of Association of Official Analytical Chemists, 13 ed., approved by the Director of the Office of the Federal Register on August 18, 1981, and incorporation by reference of the Food Chemicals Codex, 3d ed., approved by the Director of the Office of the Federal Register on August 18, 1981.

[FR Doc. 81-25547 Filed 9-3-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 452

[Docket No. 81N-0226]

Antibiotic Drugs; Erythromycin Enteric-Coated Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the certification of a new strength of erythromycin enteric-coated tablet. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective September 4, 1981; comments, notice of participation, and request for hearing by October 5, 1981; data, information, and analyses to justify a hearing by November 3, 1981.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, Bureau of Drugs (HFD–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to providing for the certification of a new strength (333 milligrams) of erythromycin enteric-coated tablet. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when the drug is used as directed in the labeling and that the regulations should be amended in Part 452 (21 CFR Part 452) to provide for its certification.

The agency has determined pursuant to 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742), that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

PART 452—MACROLIDE ANTIBIOTIC DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 507, 701 (f) and (g), 52 Stat. 1055–1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371 (f) and (g))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 452 is amended in § 452.110b by revising the second sentence in paragraph (a)(1) to read as follows:

§ 452.110b Erythromycin enteric-coated tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* * * * Each tablet contains 100, 250, or 333 milligrams of erythromycin. * * *

* * * * *

This regulation announces standards that FDA has accepted in a request for approval of an antibiotic drug. In accordance with the conditions for certification in section 507 of the act, FDA permits the manufacturer to market this drug on a "release" status pending the regulation's becoming effective. Because this regulation is not controversial and because when effective it provides notice of accepted standards and permits earlier certification of regulated products, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The amendment, therefore, is effective upon the date of publication in the **Federal Register.**

However, interested persons may, on or before October 5, 1981, submit written comments on this rule to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may file objections to it, request a hearing, and show reasonable grounds for the hearing. Any person who decides to seek a hearing must file (1) on or before October 5, 1981, a written notice of participation and request for hearing, and (2) on or before November 3, 1981, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 430.20. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and