§ 221.120 Effect of suspension by Board.

(a) *Suspended matter not to be used.* A rate, fare, charge, or other tariff provision which is suspended by the Board, under authority of section 1002 of the Act, shall not be used during the period of suspension specified by the Board's order.

* * * * *

(Sec. 204(a) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743; 49 U.S.C. 1324. Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989; 49 U.S.C. 1324 (note).)

By the Civil Aeronautics Board.

JAMES C. SCHULTZ,
General Counsel.

[FR Doc.77-10778 Filed 4-11-77;8:45 am]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-13419; File No. 57-609]

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

Uniform Net Capital Rule

AGENCY: Securities and Exchange Commission.

ACTION: Rule amendment; solicitation of public comment.

SUMMARY: Extends from April 1, 1977 until July 1, 1977 the existing suspension of the treatment of short term commercial paper prescribed by the Commission's uniform net capital rule. The Commission's action reflects its judgment that further public comment is needed to complete its reevaluation of the two ratings standard.

EFFECTIVE DATES: Amendment effective immediately; comments on or before: May 1, 1977.

ADDRESSES: Written comments, submitted in triplicate, should be addressed to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 500 North Capitol St., Washington, D.C. 20549.

FOR FURTHER INFORMATION CONTACT:

Daniel J. Piliero II, Associate Director, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549. (202) 755-1390.

SUPPLEMENTARY INFORMATION: Rule 15c3-1 [17 CFR 240.15c3-1] ("section 240.15c3-1") under the Securities Exchange Act of 1934 prescribes uniform net capital requirements applicable to substantially all brokers and dealers. For purposes of computing net capital, § 240.15c3-1(c)(2)(vi) prescribes certain percentage deductions from the current market value of securities carried in the accounts of a broker or dealer, known as "haircuts," which are intended to reflect the market risk inherent in the positioning of particular types of securities. In this connection, pursuant to the original version[1] of § 240.15c3-1(c)(2)(vi)(E), short term commercial paper[2] which bears a fixed rate of interest or which is sold at a discount, and which is ranked in one of the three highest ranking categories by at least two nationally recognized statistical rating services, receives haircuts graduating proportionately with time to maturity to a maximum of 3/8 of 1%.

In Securities Exchange Act Release No. 13125 (Dec. 30, 1976) (42 FR 2060 (Jan. 10, 1977)) (Release No. 13125) the Commission amended section 240.15c 3-1(c)(2)(vi)(E) to require no more than one such rating during the period expiring April 1, 1977, and sought public comment responsive to certain questions relating to the present contours of that provision. In general, these questions solicited the views of all interested members of the public concerning whether there is merit in the contention of some persons that it would be appropriate that § 240.15c3-1(c)(2)(vi)(E) be revised to modify or supplement that provision's two ratings standard.[3]

Release No. 13125 evoked a substantial response from members of the public, and the Commission's reevaluation of § 240.15c3-1(c)(2)(vi)(E) has benefited accordingly. However, the variety of views emergent from the public's comments, together with indications that additional persons desire to address themselves to the questions raised in Release No. 13125, suggest to the Commission that it is appropriate to solicit further public comment before it concludes its reevaluation of § 240.15c3-1(c)(2)(vi)(E). Accordingly, the Commission has decided to receive further public comment until May 1, 1977, during which time interested members of the public are invited to submit their views concerning this matter. In order to afford the Commission sufficient time to complete its analysis of the public's response, it has determined to amend § 240.15c3-1(c)(2)(vi)(E) to extend until July 1, 1977 the temporary qualified suspension thereof announced in Release No. 13125.

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[1] See Securities Exchange Act Release No. 11497 (June 26, 1975), 40 FR 29795 (July 16, 1975).

[2] For purposes of § 240.15c3-1, commercial paper is "short term" if it has a scheduled maturity at date of issue not exceeding nine months, exclusive of days of grace or any renewal thereof the maturity of which is likewise limited. See § 240.15c3-1(c)(2)(vi)(E). Such commercial paper is excluded from the statutory definition of "security" found in section 3(a)(10) of the Exchange Act, 15 U.S.C. 78c(a)(10) (1970).

[3] The public comment period established by Release No. 13125 expired on February 15, 1976.

STATUTORY BASIS AND COMPETITIVE CONSIDERATIONS

Pursuant to the Securities Exchange Act of 1934, and particularly Sections 15(c)(3) and 23(a) thereof, 15 U.S.C. 78o(c)(3), 78w(a), the Commission amends section 240.15c3-1 in Part 240 of Chapter II of Title 17 of the Code of Federal Regulations in the manner set forth below. The Commission finds that any burden imposed upon competition by this action is necessary and appropriate in furtherance of the purposes of the Act, and particularly to implement the Commission's continuing mandate under Section 15(c)(3) thereof, 15 U.S.C. 78o(c)(3), to provide minimum safeguards with respect to the financial responsibility of brokers and dealers.

PUBLIC PROCEDURE AND EFFECTIVE DATE

The amendment to § 240.15c3-1(c)(2)(vi)(E) must become effective on April 1, 1977, if the temporary qualified suspension it effects is to achieve its purpose of mantaining the presently applicable capital treatment of short term commercial paper, which treatment otherwise expires on that date. The Commission therefore finds that notice and public procedure respecting such amendment would be contrary to the public interest within the meaning of 5 U.S.C. 553(b)(3)(B) (1970). Furthermore, such amendment constitutes a substantive rule relieving a restriction within the meaning of 5 U.S.C. 553(d)(1) (1970); therefore, publication thereof need not be made not less than thirty days before its effective date.

REQUEST FOR COMMENTS

All interested persons are invited to submit, in triplicate, their written views and comments addressed to the following questions:

1. Are there uniform criteria which could be used to identify high quality commercial paper?

2. What use does the marketplace for short term commercial paper of high quality make of the credit rating or ratings borne by long term secured or unsecured debt of an issuer in determining the advisability of dealing in short term commercial paper of that issuer?

3. In lieu of one or both of the two ratings presently required, what other criteria could be employed to judge the marketability of short term commercial paper of high quality?

4. Would it be appropriate to establish a range of short term commercial paper haircuts lying between the percentage levels contemplated by the present §§ 240.15c3-1(c)(2)(vi)(E) and 240.15c3-1(c)(2)(vi)(J)? If so, in what circumstances would it be appropriate to apply such an intermediate range of haircuts to positions in short term commercial paper? What would be the appropriate percentage levels of such an intermediate range of haircuts?

All communications should be addressed to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549, no later than May 1, 1977. Reference should be made to File No. S7-609. All comments received will be available for public inspection.

TEXT OF AMENDMENTS

The amendments to § 240.15c3-1 are as follows:

§ 240.15c3-1 Net capital requirements for brokers or dealers.

* * * * *

(c) * * *
(2) * * *
(vi) * * *

(E) *Commercial paper, bankers acceptances and certificates of deposit.* In the case of any short term promissory note or evidence of indebtedness which has a fixed rate of interest or is sold at a discount, and which has a maturity date at date of issuance not exceeding nine months exclusive of days of grace, or any renewal thereof, the maturity of which is likewise limited and is rated in one of the three highest categories by at least two of the nationally recognized statistical rating organizations (*Provided*, That effective January 1, 1977, and until July 1, 1977, this paragraph shall be deemed to require only one such rating), or in the case of any negotiable certificates of deposit or bankers acceptance or similar type of instrument issued or guaranteed by any bank as defined in Section 3(a)(6) of the Securities Exchange Act of 1934, the applicable percentage of the market value of the greater of the long or short position in each of the categories specified below are:

(*1*) Less than 30 days to maturity—0%.

(*2*) 30 days but less than 91 days to maturity ⅛ of 1%.

(*3*) 91 days but less than 181 days to maturity ¼ of 1%.

(*4*) 181 days but less than 271 days to maturity ⅜ of 1%.

(*5*) 271 days but less than 1 year to maturity ½ of 1%; and

(*6*) With respect to any negotiable certificate of deposit or bankers acceptance or similar type of instrument issued or guaranteed by any bank, as defined above, having 1 year or more to maturity, the deduction shall be on the greater of the long or short position and shall be the same percentage as that prescribed in paragraph (c)(2)(vi)(A) of this section.

* * * * *

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

MARCH 31, 1977.

[FR Doc.77-10584 Filed 4-11-77;8:45 am]

Title 19—Customs Duties

CHAPTER I—UNITED STATES CUSTOMS SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 77-103]

PART 159—LIQUIDATION OF DUTIES

COUNTERVAILING DUTIES—UNWROUGHT ZINC FROM SPAIN

Correction

In FR Doc. 77-10478 appearing at page 18587 in the issue for Friday, April 8, 1977, the effective date given as April 18, 1977" should have read "April 8, 1977".

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Recodification Docket No. 17; Docket No. 77N-0032]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

Reorganization and Republication; Correction

AGENCY: Food and Drug Administration, HEW.

ACTION: Correction.

SUMMARY: This document corrects a final rule that appeared at page 15553 in the FEDERAL REGISTER of Tuesday, March 22, 1977, (FR Doc. 77-7949).

EFFECTIVE DATE: March 22, 1977.

FOR FURTHER INFORMATION CONTACT:

John Richards, 202-443-2994.

The following corrections are made:

1. On page 15576, left column, § 10.40 *Promulgation of regulations for the efficient enforcement of the law* is corrected in paragraph (e)(2) by changing "§ 12.5(b)(2)" to read "§ 12.20(b)(2)."

2. On page 15577, right column, § 10.50 *Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing* is corrected in paragraph (a)(2) by changing "12.5" to read "12.20."

3. On page 15584, right column, § 10.105 *Representation by an organization is* corrected in paragraph (d) by changing "12.5" to read "12.20."

4. On page 15586, § 12.22 *Filing objections and requests for a hearing on a regulation or order* is corrected in the introductory text of paragraph (a) by changing "§ 12.5(d)" to read "§ 12.20(d);" in paragraph (a)(1) by changing "§ 12.5(d)" to read "§ 12.20(d);" in the introductory text of paragraph (b) by changing "§ 12.5(b)" to read "§ 12.20(b);" in paragraph (c) by changing "§ 12.5(d) or § 12.20(b)" to read "§ 12.20(d) or § 12.21(b);" and in paragraph (d) by changing "§ 12.5(a)(2)" and read "§ 12.20(a)(2)."

5. On page 15586, right column, § 12.24 *Ruling on objections and requests for hearing* is corrected in paragraph (b)(6) by changing "§ 12.20" to read "12.21" and in paragraph (d) by changing "12.5" to read "12.20."

6. On page 15586, right column, § 12.26 *Modification or revocation of regulation or order* is corrected by changing "12.5" in both places to read "12.20."

7. On pages 15586 and 15587, § 12.28 *Denial of formal evidentiary public hearing in whole or in part* is corrected in the introductory text by changing "12.5" to read "12.20;" in paragraph (b)(1)(ii) by changing "12.5" to read "12.20;" and in paragraph (b)(2)(ii) by changing "12.20" to read "12.21."

8. On page 15587, § 12.30 *Judicial review after waiver of hearing on a regulation* is corrected in paragraph (a) by changing "§ 12.5(d)" to read "§ 12.20(d)."

9. On page 15588, § 12.35 *Notice of hearing; stay of action* is corrected in paragraph (a) by changing "12.5" to read "12.20."

10. On page 15588, § 12.37 *Effective date of a regulation* is corrected in paragraph (a) by changing "§ 12.5(e)" to read "§ 12.20(e)."

11. On page 15588, § 12.38 *Effective date of an order* is corrected in the introductory text of paragraph (a) and in paragraph (b) by changing "§ 12.20(b)" to read "§ 12.21(b)."

12. On page 15594, left column, § 12.100 *Administrative record of a formal evidentiary public hearing* is corrected in paragraph (a)(2) by changing "§ 12.5" to read "12.20."

Dated: April 4, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-10608 Filed 4-11-77;8:45 am]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 76P-0500]

PART 135—FROZEN DESSERTS

Revision of Standards of Identity for Ice Cream, Ice Milk, Sherbet, and Water Ices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Commissioner of Food and Drugs revises the standards of identity for ice cream, ice milk, sherbet, and water ices to (1) provide for full ingredient declaration for all of the frozen desserts; (2) provide for the use of any safe and suitable ingredient; and (3) provide for replacing the longstanding use of a milk solids nonfat minimum with a protein minimum.

EFFECTIVE DATES: 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 June 13, 1977 and all products initially introduced into interstate commerce on or after July 1, 1979 shall fully comply; objections by May 12, 1977.

ADDRESS: Written objections to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF–415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20205, 202–245–1155.

SUPPLEMENTARY INFORMATION: Based on his own initiative and on a petition filed by the International Association of Ice Cream Manufacturers (IAICM), 910 17th St. NW., Washington, D.C. 20006, the Commissioner issued a proposal, published in the FEDERAL REGISTER of July 25, 1974 (39 FR 27144), to amend the identity standards for frozen desserts. The proposal provided for the filing of comments by September 23, 1974. The comment period was subsequently extended to November 8, 1974, by notice published in the FEDERAL REGISTER of September 9, 1974 (39 FR 32562).

The July 25, 1974 notice proposed to revise and reorganize Part 20 in its entirety. The text of Part 20 appearing in the Code of Federal Regulations was recodified under Part 135, as part of a comprehensive recodification and republication of all Food and Drug Administration (FDA) regulations for food for human consumption under Subchapter B, published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302). This final regulation reflects the textual revisions, proposed July 1974, but uses the recodification numbering system and format under Part 135. For the convenience of the reader, the following table illustrates the March 1977 recodification of former Part 20, and the reformatting under Part 135 of the proposed revision of Part 20:

Old CFR section	March 15, 1977, recodification	July 25 1974, proposed revision	This final regulation
20.1	135.30	20.1	135.3
20.2	135.10	20.2	135.110
20.3	135.40	20.3	135.120
20.4	135.20	20.4	135.140
20.5	135.90	20.5	135.160
20.6	135.65	----------	----------
20.7	135.70	----------	----------
20.8	135.50	----------	----------

A total of 476 letters, containing one or more comments each, were received from industry, State governments, trade associations, and consumers. Three members of industry and 445 consumers commented favorably on the intent of the proposal to require full disclosure of all ingredients in the product by label declaration. Forty-six comments out of the 476 letters received raised specific issues and suggested changes to the proposal. A summary of the comments and the Commissioner's conclusions are discussed below.

1. Nine comments opposed the label declaration of specific stabilizers, emulsifiers, and salts in descending order of predominance. This opposition was based on two arguments. First, it was argued that the cost and/or availability of specific emulsifiers and stabilizers fluctuates enough to cause the ice cream manufacturer to substitute them interchangeably. The comments pointed out that such changes would either require the printing of new labels or cause rises in costs of raw materials, both of which result in a rise in price of the product to the consumer. Second, since the emulsifiers and stabilizers used are often blends of ingredients, it was argued that listing of all ingredients is unfair to the emulsifier and stabilizer manufacturers in that trade secrets would be revealed, competition between companies reduced, and research and development stifled due to the reticence of frozen dessert manufacturers to try new formulations once they have a supply of labels printed. The comments further stated that the type of emulsifiers and stabilizers and the amount used may vary from batch to batch; thus, the position of this ingredient on the label may not always be the same, necessitating new labels with each change.

Five alternatives were offered to this labeling requirement: (1) that ingredients used in quantities below 1 to 2 percent (0.2 to 0.5 percent in one suggestion) of the total weight of the finished product be exempt from the descending order listing requirement; (2) that ingredients be listed by class name (such as "emulsifier") in descending order, each followed by a parenthetical listing of all emulsifiers, etc., that might possibly be used; (3) that generically descriptive class terms, or groupings, be used to describe the presence of a certain kind of ingredient, e.g., the term "vegetable-derived hydrocolloids" to describe appropriate stabilizing gums, or "fatty acid ester(s)" to describe emulsifiers; (4) that ingredients be listed simply as "with safe and suitable _____," the blank to be filled with the word emulsifiers, stabilizers, or salts; and (5) that mineral salts be excluded from the label requirement on the basis that they are used as manufacturing aids only.

The Commissioner continues to adhere to the policy set forth in § 101.6 (21 CFR 101.6, formerly § 3.88 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) that the labels of standardized foods should bear "complete information" about the ingredients contained in the food. The Commissioner rejects the suggestion that stabilizers, emulsifiers, and other ingredients be exempt from ingredient labeling or the suggestion that he provide for generic labeling of these ingredients since, if he did so, consumers would not know the specific ingredients the food contains. The Commissioner has not adopted the suggestion that he permit these ingredients to be declared in an order other than that of order-of-predominance. The label designation of ingredients should be made in accordance with requirements set forth in § 101.4 (21 CFR 101.4, formerly § 1.10 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) that are generally applicable to all food, since this averts consumer confusion from variations and assures equal treatment of similar situations. Stabilizers, emulsifiers, and other ingredients are used in small amounts in many foods. If there are special difficulties in labeling these ingredients that warrant any exception from the order-of-predominance requirements, these difficulties are not unique to ice cream. If the persons who commented believe that a change should be made in the general requirements for labeling these ingredients, they should submit a petition, supported by an adequate showing, to amend § 101.4. Lastly, the comments provided no specific information to support the conclusional assertion that the label declaration of these ingredients would reveal a trade secret. The existence of a trade secret in the use of these ingredients is unlikely, but if those persons who commented submit a petition supported by adequate showing that a trade secret exists, the Commissioner will take any action necessary to protect the identity of bona fide trade secrets. The Commissioner points out that he has identified in the freedom of information regulations in § 20.61 (21 CFR 20.61, formerly § 4.61 prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)) and the explanatory preamble published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602), the elements that are essential to establish that a trade secret exists.

2. Four comments criticized the 2.7 percent protein requirement for ice cream as being lower than that of the previous standard. One of these comments questioned the calculations used to reach this protein percentage and recommended raising the minimum protein level to 3.0 percent (and to 2.5 percent from the proposed 2.2 percent when bulk flavors are used). No data, however, were submitted substantiating the need to raise the minimum protein level.

The Commissioner finds that the comments do not warrant a revision of the proposed regulation. He has carefully reviewed the calculations used to determine the protein level in ice cream under the present standard and finds no reasonable basis for believing there is an error in the manner of making the calculations. In addition, he points out that the present standard of identity for ice cream under § 135.30 (21 CFR 135.30, formerly § 20.1 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) requires a minimum of 20 percent total milk solids and a minimum of 10 percent milkfat content, with a resultant minimum requirement of 10 percent nonfat milk solids. The standard also permits a substitution of whey solids for

up to 25 percent of the required nonfat milk solids. Data from the scientific literature and certain trade associations on file with the Hearing Clerk, Food and Drug Administration, show that dried whey contains a maximum of 13 percent protein, and nonfat dry milk contains a maximum of 36 percent protein. Theoretically, based on these figures, a frozen dessert meeting the minimum existing requirement of 7.5 percent nonfat milk solids and 2.5 percent whey solids would contain a maximum protein level of approximately 3 per cent. The Commissioner does not believe, however, that it is appropriate to establish the protein requirement for frozen desserts at the maximum protein level that might be found in some forms of ice cream. Instead, he has examined the protein level of ice cream that would meet the minimum existing legal requirements and has set the protein level for mellorine at the average amount of that protein level. Analytical figures on file with the Hearing Clerk show that the average minimum protein level in nonfat dry milk is approximately 32 percent and that the average minimum protein level in dried whey is approximately 12 percent. Calculations based upon these average minimums project a protein level of approximately 2.7 percent for a frozen dessert complying with the existing standard and containing 7.5 percent nonfat milk solids and 2.5 percent whey solids.

The protein content of dairy ingredients varies with the breed of cattle, season, geographical location, and type of feed. Because of these fluctuations, it is more equitable to use the average minimum protein level rather than the maximum level. If the protein content were set at the higher level, manufacturers would have to add protein ingredients whenever the protein content of the particular dairy ingredients in the product fluctuated below the maximum level. Under the existing standard for ice cream, there is no minimum requirement for the amount of protein in the food. The difference between a 3 percent protein level and a 2.7 percent protein level in these foods does not amount to a significant difference in the recommended daily allowance for protein. Accordingly, there is no reasonable basis for believing that a 3 percent protein level rather than a 2.7 percent protein level is needed to ensure that ice cream does not contain significantly less protein than that found in ice cream that meets the existing standard.

The Commissioner therefore concludes that 2.7 percent protein is a reasonable minimum level of milk protein in ice cream and that the present final regulation retains this value except as necessary for the consideration of the incorporation of bulky flavors into the food and/or increased milkfat levels.

3. One comment supported the 2.7 percent protein level for ice cream. This comment further suggested, with a proposed minimum percentage, that a sliding scale for protein content in relation to milkfat content be established such that the percentage of protein may go below the 2.7 percent minimum as the percentage of milkfat rises above the minimum level.

The Commissioner has taken several considerations into account in reviewing the request for a sliding scale requirement for protein when milkfat levels above the minimum requirements are used for ice cream or ice milk. The current standards of identity for both ice cream and ice milk allow the nonfat milk solids content (the portion of the milk solids that contains the protein) to decrease as the fat levels increase above the minimum fat requirement. In the standard for ice cream, the fat range is from 10 to 14 percent, allowing a corresponding decrease from 10 to 6 percent in the amount of nonfat milk solids, the basic requirement being a minimum of 10 percent fat with a minimum of 20 percent total milk solids. Ice milk may range from 2 to 7 percent milkfat with a corresponding range of from 9 to 4 percent nonfat milk solids. The basic requirement is a minimum of 2 percent fat with a minimum 11 percent total milk solids. The published work of five experts on frozen dairy desserts on file with the Hearing Clerk shows that the practice has been to decrease the nonfat milk solids portion of frozen dairy desserts when the milkfat portion is increased. Therefore, the Commissioner concludes that it would be reasonable to establish in the ice cream and ice milk standards the following sliding scale of fat-to-protein levels:

FOR ICE CREAM

Percent milkfat:	*Minimum percent protein*
10	2.70
11	2.55
12	2.40
13	2.25
14	2.10

FOR ICE MILK

Percent milkfat:	*Minimum percent protein*
2	2.55
3	2.40
4	2.25
5	2.10
6	1.95
7	1.80

4a. One comment questioned the validity of including an official method for the determination of protein efficiency ratio (PER) in proposed § 20.2(b)(3) (§ 135.110(b)(3) (21 CFR 135.110(b)(3) of this final regulation)) since milk protein can be differentiated from other animal and plant proteins, and the quantities can be determined by approved and official methods that are both less expensive and more accurate indicators than the PER determination. It was pointed out, along with two other comments, that the figure 120 percent in the parenthetical expression "(120 percent of casein * * *)" in proposed § 20.2(a)(2) (§ 135.110(a)(3) of this final regulation) is incorrect and should be 108 percent. All three comments recommended deleting the expression altogether.

The Commissioner acknowledges the error in the preamble and at various points in the proposed amendments which stated that "the PER of the protein in the finished food is not less than that of whole milk protein (120 percent of casein as determined by the method prescribed in the regulation)." The "120 percent" should have read "108 percent." Therefore, the corrections have been made in the standard. The Commissioner rejects the suggestion to remove the requirement as to quality of the protein. Since whole milk protein has a PER of 108 percent of casein and there are other milk-derived ingredients that have a lower PER, such as casein with a PER of 100 percent, there is reason to retain this value.

4b. In addition, one comment indicated confusion about the requirement, found both in the standard of identity for mellorine published elsewhere in this issue of the FEDERAL REGISTER and in this document, that the food have a specified PER as determined by a certain method of analysis.

The Commissioner advises that the regulation requires foods to meet the specified PER value, but it does not independently require use of the official method of analysis. The regulation specified an official method of analysis solely to provide an authoritative means of resolving uncertainties and disputes in questionable cases. The manufacturer need not incur the expense of using the official method of determining the PER value so long as he correctly determines that the food satisfies the PER value specified in the regulation as determined by the official method.

5. Three comments objected to the elimination of the maximum whey solids limit. It was argued that the use of whey lowers the nutritional profile of the product, that whey may be substituted for the more expensive forms of nonfat milk solids with no concurrent decrease in price of the product, and, that increased quantities of whey may reduce the textural properties of the stored product.

The Commissioner concludes that all forms of safe and suitable milk-derived ingredients should be allowed to be used in making ice cream and related frozen desserts. The effect of the 2.7 percent minimum milk protein requirement for ice cream will be to remove the need for the current limitation on the amount of whey that can be used in the food. A further requirement is that the quality of the 2.7 percent protein must be equivalent to whole milk protein at a PER of 108 percent of casein. The minimum quantity and quality requirements of the present ice cream standard in § 135.30 (formerly § 20.1 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) assure the consumer that the nutritional profile of ice cream, from a milk protein standpoint, will not be lowered. To compare the relative amounts of calcium and phosphorus present when all of the nonfat milk solids of ice cream are obtained from nonfat dry milk and when 25 percent

and 40 percent of sweet whey or acid whey are substituted for nonfat dry milk, the following table is provided:

Calcium and Phosphorus Levels—Percent of US RDA supplied by 58 gram (2 oz avdp or ¼ fl oz) serving

Percent nonfat milk solids in frozen dessert mix			Percent of US RDA[1]	
Nonfat dry milk solids	Sweet whey solids	Acid whey solids	Calcium	Phosphorus
10.0	.....	.....	7.9	6.1
7.5	2.5	.....	6.9	5.7
7.5	.....	2.5	8.0	5.8
6.0	4.0	.....	6.3	6.0
6.0	.....	4.0	8.1	6.0

[1] Based on US RDA of 1,000 mg each of calcium and phosphorus for adults.

It should be understood that the present ice cream standard in § 135.30 (formerly § 20.1 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) permits up to 25 percent of the required 10 percent nonfat milk solids to be substituted with whey solids. Comparing the 25 percent whey substitution figures in the table above with the technologically feasible 40 percent whey substitution figures, it is apparent there is no significant nutritional difference in the US RDA availability of calcium and phosphorus. Even if complete substitution of the required nonfat milk solids with whey solids becomes technologically feasible, no significant nutrition differences in the US RDA availability of calcium and phosphorus would result.

No adverse textural effects have occurred when whey has been used in amounts up to 50 percent of the required 10 percent nonfat milk solids. Studies have shown that the potential problem of sandiness in ice cream, due to the high level of lactose in whey, has not occurred. Judicious use of stabilizers in the ice cream has been held a major factor in overcoming this problem. In addition, partially or completely delactosed whey may be utilized to assist in the elimination of the potential problem of sandiness in ice cream when large amounts of whey solids are substituted for nonfat dry milk in the manufacture of ice cream.

The Commissioner concludes that the arguments against elimination of the maximum whey solids limit are not supported. Therefore, there will be no limitation on the amount of whey that can be used. Rather, the minimum limitations on total percent protein and the quality of that protein (minimum PER of 108) will remain in the standards.

6. One comment questioned whether the substitution of the term "safe and suitable" for specific ingredients and limitations on those ingredients within the regulation will provide the consumer with adequate protection and information. Two additional comments advocated reinstating a list of approved ingredients and limits of use within the standards.

The Commissioner points out that since all ingredients to be used in ice cream would be considered under the "safe and suitable" definition in paragraph (d) of § 130.3 (21 CFR 130.3, formerly § 10.1, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) those ingredients which are deemed not suitable because they change the basic character of the food may not be used since they do not perform an appropriate function in the food. Ingredients that are not specifically restricted by the standard of identity for ice cream must perform an appropriate function in the food and cannot be used at a level higher than necessary to achieve that intended purpose in the food. Reinstating a list of approved ingredients inhibits the flexibility of manufacturers to meet market needs of the consumer. Further, it is the Commissioner's opinion that the requirements for label declaration of all ingredients set forth in these standards will provide the consumer with the desired information as to the actual ingredients used to manufacture the food. Therefore, the Commissioner concludes that the revised standards of identity for frozen desserts as set forth herein will provide consumers with more protection and information.

7. One comment objected to use of the phrase "nutritive carbohydrate sweeteners" on the basis that it is contrary to FDA's "safe and suitable" substances policy, and recommended changing the phrase to read "Ice cream (sherbet, etc.) is sweetened with safe and suitable sweeteners."

The Commissioner interprets this comment to mean that use of substances such as nonnutritive sweeteners or sugar alcohols, such as sorbitol, is considered. The question has been raised several times as to whether or not the substances mannitol and sorbitol were included in the Commissioner's use of the term "carbohydrate." The Commissioner is aware that different chemical text books and scientific dictionaries may differ in their definition of the term "carbohydrate." However, for clarification, he wishes to state that mannitol and sorbitol, for the purposes of proposed § 20.2, (§ 135.110 in this final regulation) are not considered to be "carbohydrates." The Commissioner does not consider nonnutritive sweeteners or sugar alcohols to be suitable ingredients for use in the foods presently standardized as frozen desserts. Their use in lieu of sugar, for instance, would result in a change in the physical characteristics of the food. The only sweeteners permitted for use in frozen desserts under the existing standards are nutritive carbohydrate sweeteners. Furthermore, a change in the regulation to allow the use of nonnutritive sweeteners and sugar alcohols in frozen desserts should be published as a proposal, and the public should be given an opportunity for comment. If the persons who commented believe that this change is warranted, they should petition the Commissioner to amend the regulation. Accordingly, the Commissioner has retained the term "nutritive carbohydrate sweeteners" in the final regulation. Thus, nonnutritive sweeteners and sugar alcohols may not be used in frozen desserts, but all the nutritive sweeteners listed in Part 168 (21 CFR Part 168, formerly Part 26, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) may be used as well as other safe and suitable nutritive carbohydrate sweeteners.

8. One comment objected to the requirement that water be listed as an ingredient where it is used to reconstitute a concentrated or dried ingredient, such as nonfat dry milk, on the basis that no more water is added than is necessary to restore the food to its original form. Furthermore, depending on the availability of ingredients, none may have to be reconstituted, thus making the presence of water in the ingredients list inaccurate. This comment suggested the labeling alternative "milk products (nonfat milk and milkfat)" which it felt would be both informative and not misleading to the consumer.

The Commissioner points out that he provided an option as to the manner in which dairy ingredients could appear on the label. One method is to follow the requirements of § 101.4; the other is that sources of milkfat or nonfat milk solids may be declared in descending order of predominance by use of all of the terms "water," "milkfat," and "nonfat milk solids." The Commissioner, having further reviewed this issue, concludes that since milkfat and nonfat milk solids are commonly understood to be the basic division of whole milk solids, it seems reasonable that when various forms of skim milk, milk, cream, or butterfat (as described in § 101.4(b) (3), (4), (8) and (9), published in the FEDERAL REGISTER of January 6, 1976 (41 FR 1156)) are used as the source of the milkfat and nonfat milk solids of a frozen dessert, the words "milkfat" and "nonfat milk" would be sufficient for the label declaration of such ingredients. Therefore, proposed § 20.2(d) (§ 135.110(d) of this final regulation) of the ice cream standard of identity is revised accordingly. When other dairy ingredients, in various forms (e.g., liquid, condensed or dried) such as buttermilk, whey, casein, caseinates or modified whey products are used, they too must be declared in the ingredient statement. Such ingredients must be declared by name in accordance with Part 101 (21 CFR Part 101, formerly Part 1, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)).

9. One comment objected to the term "nonfat milk solids" as used in paragraph(a)(6) of proposed § 20.4 (§ 135.140 (21 CFR 135.140) of this final regulation) on the basis that it may be narrowly interpreted to mean nonfat dry milk. The comment suggested that the term "nonfat milk-derived solids" be substituted.

The Commissioner believes that, although the term "nonfat milk solids" is a generic term, it could be interpreted to mean nonfat dry milk. Since the actual source could be skim milk, skim milk derivatives, whey, and whey derivatives,

the Commissioner concludes that the term "nonfat milk-derived solids" would be more definitive, and he amends paragraph (a)(2) of proposed § 20.4 (§ 135.14 of this final regulation) accordingly.

10. One comment stated that there is a current need for a "bulky flavor reduction" provision in a standard for ice milk in order to maximize economy in production.

The Commissioner agrees, and he amends the ice milk standard to include the statement "The provision for reduction in milkfat and protein content from the addition of bulky flavors in proposed § 20.2(a) (§ 135.110(a) of this final regulation) applies except that in no case will the milkfat content be less than 2 percent, nor the protein content less than 1.75 percent."

11. One comment objected to the proposed "generic groupings" method of labeling ingredients on the basis that it does not allow the consumer to see, on the label, the specific ingredients that might constitute a generic term such as "milkfat."

The Commissioner issued final regulations, published in the FEDERAL REGISTER of January 6, 1976 (41 FR 1156), concerning label declaration of ingredients. Ingredients that are required to be declared on the label of a food must be declared in accordance with § 101.4. Section 101.4(b) specifies that the name of an ingredient shall be a specific name and not a collective (generic) name; however, it does provide for certain exceptions. Under § 101.4(b)(3), various forms of skim milk (e.g., liquid, condensed or dried) may be declared as "skim milk" or "nonfat milk"; under § 101.4(b)(4), various forms of milk may be declared as "milk"; under § 101.4(b)(6), various forms of buttermilk as "buttermilk"; under § 101.4(b)(7), various forms of whey as "whey"; under § 101.4(b)(8), various forms of cream as "cream"; and under § 101.4(b)(9), various forms of butterfat as "butterfat." All of the above dairy ingredients contain varying amounts of milkfat and nonfat milk solids which are utilized to meet the minimum requirements of the various frozen dessert standards for milkfat and nonfat milk solids. The Commissioner concludes that the labeling requirements of the proposed frozen dessert standards provide adequate ingredient labeling information to the consumer without confusing the consumer with different forms of the same ingredients.

12. One comment expressed the opinion that the present method of labeling added colors is deceptive and suggested that it be made mandatory that wherever a statement concerning artificial flavoring appears on the carton, a statement about artificial colors used also appear.

The Commissioner points out that section 403(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(k)) specifically exempts the declaring of artificial color on the label of ice cream. The act does not provide such an exemption for the declaration of artificial flavoring. The Commissioner, however, does recommend voluntary declaration of artificial coloring since, in his opinion, such declaration would be in the best interests of the consumer.

13. One comment recommended that artificial colorings and characterizing flavors be prohibited in ice milk packed in containers larger than ½ gallon. This recommendation was made to prevent consumers from being deceived by the substitution of ice milk for ice cream.

The Commissioner points out that there are more appropriate means of regulating the potential problems of substitution than prohibiting the use of colors and flavorings; that is, any substitution of ice milk for ice cream would be unlawful.

14. One comment suggested that salt and other sodium compounds be limited in frozen foods to provide "salt free" dieters with a more varied diet of easily available foods.

The Commissioner points out that it is not his intention to provide a standard for special dietary frozen desserts which would be subject to the requirements of § 105.69 (21 CFR 105.69, formerly § 125.9, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)). He further points out that the amount of salt used would be self-limiting in that adding too much salt or other sodium compounds would make the product unpalatable to the consumer. Therefore, for these reasons, the Commissioner concludes that the use of salt and/or other sodium compounds should not be restricted in the regulation.

15. One comment requested that the proposed three-flavor category for labeling of ice cream and frozen desserts be retained. No adverse comments were received.

The Commissioner agrees and is retaining the three-flavor category for labeling ice cream and frozen desserts as proposed.

16. Eleven comments advocated that the percentage of each ingredient used be included in the label declaration. Several specifically requested that the percentage of butterfat be noted on the label.

The proposed standards of identity for frozen desserts specify minimum levels for the characterizing ingredients of the food. In addition, a minimum level of food solids is required as well as a minimum weight per unit volume for the food. The labeling requirements of the standards also require that the ingredients be listed by common or usual name in descending order of predominance by weight as provided for in Part 101. Indications are that many manufacturers of frozen deserts will voluntarily provide nutrition labeling on the containers of their products. The Commissioner concludes that this regulation provides adequate labeling information to the consumer and that the declaration of the percent of each ingredient contained in the food will not be required. Since no data were presented for percent ingredient labeling and, further, since only in Part 102 (21 CFR Part 102) are there specific provisions for such labeling, the standards concerning this matter will remain as proposed.

17. Three comments requested that either the weight of the package or the percent overrun be noted on packages of ice cream or other frozen desserts. One of the comments also suggested that air be included in the ingredient list for ice cream or other frozen desserts.

The Commissioner advises that in manufacturing ice cream it is practicable to control the quantity of overrun. The current frozen dessert standard limits the overrun by establishing a minimum weight per gallon for the finished ice cream. It also requires the weight of ice cream to be not less than 4.5 pounds per gallon. This is effective in preventing the excessive incorporation of air, i.e., overrun, and is reasonable. Therefore, the Commissioner believes that no useful purpose would be served by requiring the label declaration of weight or percent overrun on packages of ice cream and/or the declaration of air in the ingredient list.

18. Three comments requested open-code dating on all frozen dessert packages. One of the comments stated that the proposed amendment to the standard of identity for frozen desserts should include (1) packaging date, (2) pull date, (3) instructions for home storage, and (4) processing plant numbers.

The Commissioner is of the opinion that this comment is beyond the scope of this document, and, further, that there have been no compelling arguments given to provide for these label declarations for frozen desserts. Therefore, any change in this regard must come by an appropriate petition to amend these regulations.

19. One comment was received regarding the limitation on the bacteria content in ice cream.

The Commissioner concludes that this comment is beyond the scope of this document, and further, that no case has been made to amend the current proposal at this time. Therefore, any change in this regard must come by an appropriate petition to amend these regulations.

20. One comment requested a hearing on the proposal, asserting that "Elimination of the 25 percent maximum use of whey along with reduction in final protein content to 2.7 percent would likely destroy the nutritional profile of ice cream."

The Commissioner has discussed the elimination of the maximum whey solids limit and the establishment of a minimum 2.7 percent protein content elsewhere in this preamble and has concluded that these amendments should be adopted as proposed. The Commissioner advises, however, that any person who is adversely affected by the regulation if placed in effect may, until May 12, 1977 file objections and request a hearing upon such objections.

It has been brought to the Commissioner's attention that there was a typo-

graphical error in the proposal. Therefore, the following correction is made: proposed § 20.1 (§ 135.3 (21 CFR 135.3) of this final regulation) which states "For the * * * a pasteurized mix is one every particle of which has been heated * * * (* * * equivalent thereto in microbial destruction):" is changed to read "For the * * * a pasteurized mix is one in which every particle of the mix has been heated * * * (* * * equivalent thereto in microbial destruction):". In addition, modifying the wordage of the existing standard for water ices in proposed § 20.5 (§ 135.160 of this final regulation) to reference the standard for sherbet in proposed § 20.4 (§ 135.140 of this final regulation) inadvertently caused water ice mix to be considered a pasteurized mix. Since the current standard of identity for water ices did not require pasteurization of the mix and there is no need to require it now, proposed § 20.5(a) (§ 135.160(a) of this final regulation) is modified to read "Water ices are * * * in the same manner prescribed in § 135.140 for sherbets, except that the mix need not be pasteurized, and * * * is used." In § 135.140(a)(1) of the final regulation (proposed § 20.4(a)(1)), the words "and/or milk-derived ingredients alone or in combination" are added to be consistent with the wordage of other frozen dessert standards of Part 135.

Having considered the information submitted by the petitioner, the comments received, and other relevant material, the Commissioner concludes that it will promote honesty and fair dealing in the interest of consumers to adopt the proposal, with modifications, as set forth below.

The Commissioner has considered the environmental effects of the issuance or amendment of food standards and has concluded in paragraph (d)(4) of § 25.1 (21 CFR 25.1, formerly § 6.1, prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)) that food standards are not major agency actions significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required for this final regulation.

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 (21 CFR 5.1): *It is ordered*, That §§ 135.10, 135.20, 135.30, 135.40, 135.65, 135.70, and 135.90 be revised and reissued as §§ 135.3, 135.110, 135.120, 135.140, and 135.160, to read as follows:

Subpart A—General Provisions

Sec.

135.3 Definitions.

Subpart B—Requirements for Specific Standardized Frozen Desserts

135.110 Ice cream and frozen custard.
135.120 Ice milk.
135.140 Sherbet.
135.160 Water ices.

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

Subpart A—General Provisions

§ 135.3 Definitions.

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

Temperature:	Time
155° F.	30 min.
175° F.	25 sec.

Subpart B—Requirements for Specific Standardized Frozen Desserts

§ 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 safe and suitable ingredients including, but not limited to, milkfat and nonfat milk solids, and/or other milk-derived ingredients alone or in combination; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with nutritive carbohydrate sweeteners and may or may not be characterized by the addition of flavoring ingredients.

(2) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milkfat, nor less than 2.7 percent protein having a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein), except that when it contains milkfat at 1 percent increments above the 10 percent minimum, it may contain the following milkfat-to-protein levels:

Percent milkfat:	Minimum percent protein
10	2.70
11	2.55
12	2.40
13	2.25
14	2.10

Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. In no case shall the milkfat content of the finished food be less than 8 percent or the protein content be less than 2.2 percent, or, in the case of frozen custard, shall the content of egg yolk solids be less than 1.12 percent. The protein to meet the minimum protein requirement shall be provided by milk solids not fat and/or other milk-derived ingredients. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (c)(1) of this section.

(3) When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Methods of analysis.* Fat and protein content, and the PER shall be determined by the following methods contained in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975.[1]

(1) Fat content shall be determined by the method: "Fat; Roese-Gottlieb Method—Official Final Action," section 16.228.

(2) Protein content shall be determined by one of the methods: "Nitrogen—Official Final Action," Kjeldahl Method, section 16.226, or Dye Binding Method, section 16.227.

(3) PER shall be determined by the method: "Biological Evaluation of Protein Quality-Official Final Action," sections 39.166–39.170.

(c) *Nomenclature.* (1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard" or "french ice cream" or "french custard ice cream".

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

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "VANILLA flavored", or "PEACH flavored", or "VANILLA flavored and STRAWBERRY flavored".

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

[1] Copies may be obtained from: Association of Official Analytical Chemists, Post Office Box 540, Benjamin Franklin Station, Washington, DC 20044.

name of the characterizing flavor, e.g., "artificial VANILLA", or "artificially flavored STRAWBERRY" or "artificially flavored VANILLA and artificially flavored STRAWBERRY".

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

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

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

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

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

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (c) (5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "artificially flavored banana-almond ice cream". However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "banana-almond flavored ice cream".

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

(d) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b) (3), (4), (8), and (9) of this chapter are used or alternatively as permitted in § 101.4 of this chapter. Pursuant to section 402(k) of the Federal Food, Drug, and Cosmetic Act artificial color need not be declared in ice cream. Voluntary declaration of such color in ice cream is recommended.

§ 135.120 Ice milk.

(a) *Description.* Ice milk is the food prepared from the same ingredients and in the same manner prescribed in § 135.110 for ice cream and complies with all the provisions of § 135.110 including the requirements for label statement of optional ingredients), except that:

(1) Its content of milkfat is more than 2 percent but not more than 7 percent.

(2) The provision for reduction in milkfat and protein content from the addition of bulky flavors in § 135.110(a) applies, except that in no case will the milkfat content be less than 2 percent, nor the protein content less than 1.75 percent. When the milkfat content increases in increments of 1 percent above the 2 percent minimum, it may contain the following milkfat-to-protein levels:

Percent milkfat:	*Minimum percent protein*
2	2.55
3	2.40
4	2.25
5	2.10
6	1.95
7	1.80

(3) The quantity of food solids per gallon is not less than 1.3 pounds.

(4) When any artificial coloring is used in ice milk, directly or as a component of any other ingredient, the label shall bear the statement "artificially colored", "artificial coloring added", "with added artificial color", or "_____, an artificial color added", the blank being filled in with the common or usual name of the artificial color; or in lieu thereof, in case the artificial color is a component of another ingredient, "_____ artificially colored".

(5) If both artificial color and artificial flavoring are used, the label statements may be combined.

(b) *Nomenclature.* The name of the food is "ice milk".

§ 135.140 Sherbet.

(a) *Description.* (1) Sherbet is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including but not limited to milkfat and nonfat milk solids, and/or other milk-derived ingredients alone or in combination, and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened with nutritive carbohydrate sweeteners and is characterized by the addition of one or more of the characterizing fruit ingredients specified in paragraph (b) of this section or one or more of the nonfruit characterizing ingredients specified in paragraph (c) of this section.

(2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2 percent, the nonfat milk-derived solids content not less than 1 percent and the total milk or milk-derived solids content is not less than 2 percent nor more than 5 percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.35 percent.

(b) The optional fruit characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contribut-

ing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) The optional nonfruit characterizing ingredients referred to in paragraph (a) of this section include but are not limited to the following:

(1) Ground spice or infusion of coffee or tea.

(2) Chocolate or cocoa, including sirup.

(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

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

(i) The name of each fruit sherbet is "_____ sherbet", the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) The name of each nonfruit sherbet is "_____ sherbet", the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint", except that if the characterizing flavor used is vanilla, the name of the food is "_____ sherbet", the blank being filled in as specified by § 135.110(c)(2) and (5)(i).

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

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

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

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

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

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

(g) Label declaration: Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in § 135.140 for sherbets, except that the mix need not be pasteurized, and complies with all the provisions of § 135.140 (including the requirements for label statement of optional ingredients) except that no milk or milk-derived ingredient and no egg ingredient, other than egg wihte, is used.

(b) *Nomenclature.* The name of the food is "_____ ice", the blank being filled in, in the same manner as specified in § 135.140(d)(1) (i) and (ii), as appropriate.

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 12, 1977, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 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 on or before June 13, 1977 and all products initially introduced into interstate commerce on or after July 1, 1979 shall fully comply. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

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

Dated: April 4, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

NOTE.—Incorporation by reference provisions have been approved by the Director of the Office of the Federal Register March 11, 1976, and are on file in the library of that office.

[FR Doc.77-10624 Filed 4-11-77;8:45 am]

[Docket No. 75N-0368]

PART 135—FROZEN DESSERTS

Mellorine: Confirmation of Effective Date of Final Regulation Establishing a Standard of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The effective date for the regulation that established a standard of identity for mellorine is confirmed.

DATES: Compliance with the regulation, including any labeling changes required, may have begun on September 23, 1974, and all products initially introduced into interstate commerce on or after July 1, 1979 shall fully comply.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFC-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a final regulation in the FEDERAL REGISTER of July 25, 1974 (39 FR 27128) that established a standard of identity for mellorine, terminated the rule making procedure to establish a standard of identity for parevine, and revoked 21 CFR 3.39. The final regulation provided that any person who would be adversely affected could, at any time on or before August 26, 1974, file written objections and request a hearing.

The July 1974 standard of identity for mellorine was promulgated under § 20.8