missioner (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (d)(1)(xv) and deleting paragraphs (d)(1) (v) and (vi) and marking them "reserved," as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *
(1) * * *

* * * * *

(v) [Reserved]
(vi) [Reserved]

* * * * *

(xv) *Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel.* Established April 28, 1978.

* * * * *

Effective date. Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the FEDERAL REGISTER, May 19, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: May 12, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Comissioner for Regulatory Affairs.

[FR Doc. 78-13584 Filed 5-18-78; 8:45 am]

[4110-03]

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Advisory Committees; Establishment and Terminations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and the public advisory committee procedures (21 CFR Part 14), this document announces the establishment of one advisory committee and the termination of three others. This document adds to and deletes from the agency's list of standing advisory committees.

EFFECTIVE DATE: May 19, 1978; authority for the committee will remain in effect until amended or terminated by the Commissioner of Food and Drugs.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and § 14.40(b) (21 CFR 14.40(b)), the Food and Drug Administration (FDA) announces the establishment of the Surgical and Rehabilitation Devices Panel by the Commissioner of Food and Drugs.

The Committee will do the following: (1) Review and evaluate data concerning the safety and effectiveness of surgical and rehabilitation devices currently in use and advise the Commissioner regarding recommended classification of these devices into one of three regulatory categories; (2) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards of premarket approval category; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; (5) review classification of devices to recommend changes in classification as appropriate; (6) recommend exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (7) advise on the necessity to ban a device; and (8) respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Concurrently with the establishment, the Commissioner approved the termination of the General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, and the Physical Medicine Device Classification Panel. Under § 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of these committees.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (d)(1)(viii) and deleting paragraphs (d)(1) (xvi) and (xviii) and marking them "reserved," as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *
(1) * * *

(viii) *Surgical and Rehabilitation Devices Panel.* Established April 28, 1978.

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(xvi) [Reserved]

* * * * *

(xviii) [Reserved]

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Effective date. Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the FEDERAL REGISTER, May 19, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: May 12, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-13585 Filed 5-18-78; 8:45 am]

[4110-03]

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Advisory Committees; Establishment and Terminations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and the public advisory committee procedures (21 CFR Part 14), this document announces the establishment of one advisory committee and the termination of two others. This document adds to and deletes from the agency's list of standing advisory committees.

EFFECTIVE DATE: May 19, 1978; authority for the committee will remain in effect until amended or terminated by the Commissioner of Food and Drugs.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and § 14.40(b) (21 CFR 14.40(b)), the Food and Drug Administration (FDA) announces the establishment of the Respiratory and Nervous System Devices Panel by the Commissioner of Food and Drugs.

The Committee will review and evaluate data concerning the safety and effectiveness of respiratory and nervous system devices currently in use and advise the Commissioner re-

garding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification of devices to recommend changes in classification as appropriate; recommend exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advise on the necessity to ban a device; and respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Concurrently with the establishment, the Commissioner approved the termination of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel. Under § 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of these committees.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (d)(1)(i) and deleting paragraph (xiii) and marking it "reserved," as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(1) * * *

(i) *Respiratory and Nervous System Devices Panel.* Established April 28, 1978.

* * * * *

(xiii) [Reserved]

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Effective date. Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the FEDERAL REGISTER, May 19, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: May 12, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-13586 Filed 5-18-78; 8:45 am]

[4110-03]

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Advisory Committees; Establishment and Terminations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and the public advisory committee procedures (21 CFR Part 14), this document announces the establishment of one advisory committee and the termination of three others. This document adds to and deletes from the agency's list of standing advisory committees.

EFFECTIVE DATE: May 19, 1978; authority for the committee will remain in effect until amended or terminated by the Commissioner of Food and Drugs.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and § 14.40(b) (21 CFR 14.40(b)), the Food and Drug Administration (FDA) announces the establishment of the Clinical Chemistry and Hematology Devices Panel by the Commissioner of Food and Drugs.

The Committee will do the following: (1) Review and evaluate data concerning the safety and effectiveness of clinical chemistry, clinical toxicology, and hematology devices currently in use and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; (2) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; (5) review classification of devices to recommend changes in classification as appropriate; (6) recommend exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (7) advise on the necessity to ban a device; and (8) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Concurrently with the establishment, the Commissioner aproved the termination of the Clinical Chemistry Device Classification Panel, the Clinical Toxicology Device Classification Panel, and the Hematology Device Classification Panel. Under § 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of these committees.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (d)(1)(iii) and deleting paragraphs (d)(1) (iv) and (x) and marking them "reserved," as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d)* * *

(1)* * *

(iii) *Clinical Chemistry and Hematology Devices Panel.* Established April 28, 1978.

(iv) [Reserved]

* * * * *

(x) [Reserved]

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Effective date. Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the FEDERAL REGISTER, May 19, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: May 12, 1978

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-13587 Filed 5-18-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0118]

PART 131—MILK AND CREAM

Evaporated Milk, Sweetened Condensed Milk, Evaporated Skimmed Milk, and Sweetened Condensed Skimmed Milk; Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document establishes standards of identity for evapo-

rated skimmed milk and sweetened condensed skimmed milk and revises the standards of identity for evaporated milk and sweetened condensed milk, based on consideration of the international standards developed by the Codex Alimentarius Commission for these foods. This action will promote honesty and fair dealing in the interest of consumers and will facilitate international trade by conforming U.S. standards more closely to international standards.

DATES: Effective July 1, 1979 for all products initially introduced into interstate commerce on or after this date.

Voluntary compliance: July 18, 1978. Objections by June 19, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 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 Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a proposal in the FEDERAL REGISTER of July 19, 1977 (42 FR 37013) to amend the standards of identity for evaporated milk and sweetened condensed milk in §§ 131.130 and 131.120 (21 CFR 131.130, 131.120), respectively, and to establish new standards of identity for evaporated skimmed milk and sweetened condensed skimmed milk in §§ 131.132 and 131.122 (21 CFR 131.132, 131.122), respectively. The proposed standards were based on the recommended international standards for evaporated milk and evaporated skimmed milk (Codex Standard No. A-3 (1971))[1] and sweetened condensed milk, and sweetened condensed skimmed milk (Codex Standard No. A-4 (1971))[1] which were submitted to the United States for consideration of acceptance by the Joint Food and Agriculture Organization/World Health Organization's Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products, an auxiliary body of the Codex Alimentarius Commission.

The standards of identity set out below are being adopted as part of a program in which the United States is participating along with approximately 100 other countries to establish regional and/or worldwide food standards. The new standards of identity include (1) requirements for mandatory ingredients, (2) provisions for optional ingredients, such as safe and suitable stabilizers, emulsifiers, carriers for vitamins A and D, and characterizing flavoring ingredients, with or without coloring, and (3) requirements for label declaration of all optional ingredients except carriers for vitamins which are exempted by § 101.100(a)(3)(i) (21 CFR 101.100(a)(3)(i)). In addition, the standards of identity for evaporated milk and sweetened condensed milk are amended to provide for the use of nutritive carbohydrate sweeteners in the provision for optional characterizing flavoring. Further, for consistency with the international standards, where to do so is in accordance with FDA's policy of reasonableness and in the interest of consumers, the compositional requirements of these foods are amended to reduce the total solids requirement for evaporated milk from 25.5 percent to 25 percent by weight, and the milkfat requirement for sweetened condensed milk from 8.5 percent to 8 percent by weight.

Three comments were received in response to the proposal. One comment from the Evaporated Milk Association endorsed the proposed standard of identity for evaporated skimmed milk and the proposed revision of the standard of identity for evaporated milk. One comment from a major domestic manufacturer of sweetened condensed milk supported the proposed revision of the standard of identity for sweetened condensed milk. The third comment, from a State department of agriculture, generally supported the proposal and made several suggestions. The suggestions from the State department of agriculture and the Commissioner's responses are as follows:

1. The comment suggested that, to facilitate uniformity among standards, the composition of reduced-moisture milks should be consistent with that of fluid whole milk. Further, it explained, given the milkfat to milk solids not fat (mf/msnf) ratio for fluid milks, evaporated/condensed equivalents should maintain similar ratios, allowing for moisture reduction.

The Commissioner does not agree that there is a need to require the same mf/msnf ratio for fluid milk and evaporated and condensed milk products since the bases for the minimum requirements in the standards differ. He acknowledges that there are slight differences in the mf/msnf ratios for fluid whole milk and evaporated milk and sweetened condensed milk. In the case of whole milk, the minimum milkfat requirement of 3.25 percent and the minimum milk solids not fat requirement of 8.25 percent are based on the average minima determined for the composition of cow's milk and result in a mf/msnf ratio of 1:2.54. In the case of evaporated milk and sweetened condensed milk, the minimum milkfat and minimum milk solids requirements are based on the Codex requirements for these foods. The resulting mf/msnf ratios are 1:2.33 for evaporated milk and 1:2.50 for sweetened condensed milk. Traditionally, evaporated and sweetened condensed milks are obtained by the partial removal of water from fluid milk. Prior to removal of the water, the fat is adjusted in the fluid milk to an average rather than a minimum value. The current revisions of the standards of identity for evaporated milk and sweetened condensed milk, which are minimal, are made to effect consistency with the Codex standards for these foods. As he stated in the proposal, the Commissioner maintains that the proposed requirements are reasonable, will benefit international trade, and do not conflict with the need to promote honesty and fair dealing in the interest of consumers. The Commissioner concludes that the minimum milkfat and minimum milk solids not fat requirements for these foods should not be changed from those in the proposal.

2. The comment suggested that fluid and reduced-moisture milks should be uniformly vitamin fortified. It maintained that because the addition of vitamin D is optional in fluid milks and the addition of vitamin A is required in reduced-fat milks, addition of vitamin D to evaporated milk should be optional and the addition of vitamin A should be required for evaporated skimmed milk. The comment further stated that if regulations do not establish uniform standards for adding these vitamins to fluid and evaporated milks, the name of the standardized product should reflect the vitamin fortification (e.g., "nonfat dry milk fortified with vitamins A and D"). Thus, the comment stated, evaporated milk should be standardized as "evaporated milk fortified with vitamin D" and evaporated skimmed milk as "evaporated skimmed milk fortified with vitamins A and D".

The Commissioner does not agree that the vitamin fortification requirements for evaporated milk products should be amended simply for consistency with the requirements for fluid milk products. He notes that although vitamin D addition to fluid milks is optional, practically all such products contain added vitamin D. Further, because evaporated milk products are use in infant feeding programs, and because the practice of fortifying evaporated milk products with vitamin D is well accepted by nutritionists, he concludes that the standards of identity for evaporated milk and evaporated skimmed milk should not be changed from those in the proposal.

[1]Code of Principles Concerning Milk and Milk Products, International Standards and Standard Methods of Sampling and Analysis for Milk Products, 7th Ed. FAO/WHO Document No. CAC/M 1-1973.

The Commissioner does not agree with the suggested requirement for names such as "evaporated milk fortified with vitamin D" and "evaporated skimmed milk fortified with vitamins A and D". He maintains that the required terms which follow the name of the food in its labeling, i.e., "vitamin D" or "vitamin D added", or "vitamins A and D" or "vitamins A and D added", as appropriate, are sufficient to inform the consumer of the presence of added vitamins. He notes that the term "fortified with" is also used in the name of fluid milk products when milk solids are added, as well as in the name of nonfat dry milk fortified with vitamins A and D. The term "fortified with" in each case distinguishes the fortified product from its "unfortified" counterpart. Moreover, in the standards of identity for evaporated milk, as codified, and evaporated skimmed milk, as proposed, where fortification with vitamin(s) is mandatory and there would be no unfortified counterpart, he believes there would be no ambiguity by not requiring the name of the food to include terms such as "fortified with". The labels of evaporated milk and evaporated skimmed milk in the marketplace presently bear the names consistent with those set out in the standards of identity, and because consumers are familiar with these names, the Commissioner concludes that such a name change is unwarranted.

In consideration of the comments received, the Commissioner concludes that to establish standards of identity for evaporated skimmed milk and sweetened condensed skimmed milk based on the recommended international standards and to amend the standards of identity for evaporated milk and sweetened condensed milk, as set forth in this document, will promote honesty and fair dealing in the interest of consumers.

For the sake of clarity, several minor editorial changes have been adopted in this final rule.

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 him (21 CFR 5.1), the Commissioner amends Part 131 as follows:

1. By revising § 131.120 to read as follows:

§ 131.120 Sweetened condensed milk.

(a) *Description.* Sweetened condensed milk is the food obtained by partial removal of water only from a mixture of milk and safe and suitable nutritive carbohydrate sweeteners. The finished food contains not less than 8 percent by weight of milkfat, and not less than 28 percent by weight of total milk solids. The quantity of nutritive carbohydrate sweetener used is sufficient to prevent spoilage. The food is pasteurized and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, may be used:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Method of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975, section 16.167, under "Fat—Official Final Action."[2]

(d) *Nomenclature.* The name of the food is "Sweetened condensed milk." The word "homogenized" may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration.* The nutritive carbohydrate sweetener(s) required in paragraph (a) of this section and each of the optional ingredients specified in paragraph (b) of this section, when used in the food, shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

2. By adding § 131.122 to read as follows:

§ 131.122 Sweetened condensed skimmed milk.

(a) *Description.* Sweetened condensed skimmed milk is the food obtained by the partial removal of water only from a mixture of skim milk and safe and suitable nutritive carbohydrate sweeteners. The finished food contains not more than 0.5 percent by weight of milkfat unless otherwise indicated and not less than 24 percent by weight of total milk solids. The quantity of nutritive carbohydrate sweeteners used is sufficient to prevent spoilage. The food is pasteurized and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable characterizing flavoring ingredients, with or without coloring, and nutritive carbohydrate sweeteners may be used:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Method of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975, section 16.167 under "Fat—Official Final Action."[2]

(d) *Nomenclature.* The name of the food is "Sweetened condensed skimmed milk." The word "homogenized" may appear on the label if the food has been homogenized. If the milkfat content is over 0.5 percent by weight, the name of the food shall be accompanied by the statement "Contains ———— percent milkfat", the blank to be filled in with the fraction "½", or multiple thereof, closest to the actual milkfat content of the product. The name of the food shall be accompanied by a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of ths chapter.

(e) *Label declaration.* The nutritive carbohydrate sweetener required in paragraph (a) of this section and each of the optional ingredients specified in paragraph (b) of this section when used in the food, shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

3. By revision § 131.130 to read as follows:

§ 131.130 Evaporated milk.

(a) *Description.* Evaporated milk is the liquid food obtained by partial removal of water only from milk. It contains not less than 7.5 percent by weight of milkfat and not less than 25 percent by weight of total milk solids. Evaporated milk contains added vitamin D as prescribed by paragraph (b) of this section. It is homogenized. It is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) *Vitamin addition.* (1) Vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin A is optional, If added, vitamin A shall be present in such quantity that each fluid ounce of the food contains not less than 125 International Units thereof within limits of good maufacturing practice.

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

(1) Carriers for vitamins A and D.

(2) Emulsifiers.

(3) Stabilizers, with or without dioctyl sodium sulfosuccinate (when permitted by and complying with the provisions of § 172.810 of this chapter) as a solubilizing agent.

(4) Characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

[2]Copies may be obtained from: The Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975.[2]

(1) Milkfat-content—"Fat—Official Final Action," section 16.154.[2]

(2) Total milk solids—"Total Solids—Official Final Action," section 16.151.[2]

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 43.166–43.179.[2]

(e) *Nomenclature.* The name of the food is "Evaporated milk." The phrase "vitamin D" or "vitamin D added", or "vitamins A and D" or "vitamins A and D added", as is appropriate, shall immediately precede or follow the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name. The name of the food shall include a declaration of a the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *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.

4. By adding § 131.132 to read as follows:

§ 131.132 Evaporated skimmed milk.

(a) *Description.* Evaporated skimmed milk is the liquid food obtained by the partial removal of water only from skim milk. It contains not less than 20 percent by weight of total milk solids, and not more than 0.5 percent by weight of milkfat unless otherwise indicated. Evaporated skimmed milk contains added vitamins A and D as prescribed by paragraph (b) of this section. It may be homogenized. It is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) *Vitamin addition.* (1) Vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof within limits of good manufacturing practice.

(2) Vitamin A shall be present in such quantity that each fluid ounce of the food contains not less than 125 International Units thereof within limits of good manufacturing practice.

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

(1) Carriers for vitamin A and D.

(2) Emulsifiers.

(3) Stabilizers, with or without dioctyl sodium sulfosuccinate (when permitted by, and complying with provisions of § 172.810 of this chapter) as a solubilizing agent.

(4) Characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analyses.* The following referenced methods of analyses are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.154.[2]

(2) Total milk solids—"Total Solids—Official Final Action," section 16.151.[2]

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 43.166–43.179.[2]

(e) *Nomenclature.* The name of the food is "Evaporated skimmed milk." The phrase "vitamins A and D" or "vitamins A and D added", shall immediately precede or follow the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name. If the milkfat content is over 0.5 percent by weight, the name of the food shall be accompanied by the statement, "Contains ———— percent milkfat", the blank to be filled in with the fraction "½", or multiple thereof, closest to the actual milkfat content of the product. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *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.

Any person who will be adversely affected by the foregoing regulation may at any time on or before June 19, 1978, submit to the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 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 numbered 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. Four copies of all documents shall be submitted and shall be 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 July 18, 1978, 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)))

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 11, 1976 and is on file in the Federal Register Library.

Dated: May 11, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-13588 Filed 5-18-78; 8:45 am]

[4810-25]

Title 31—Money and Finance: Treasury

CHAPTER I—MONETARY OFFICES, DEPARTMENT OF THE TREASURY

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

Recordkeeping Required

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: This amendment requires any bank or other financial institution that sells or redeems a certificate of deposit on or after June 1, 1978, to maintain a record of the transaction which shall include the date, name, address and the taxpayer identification number of the purchaser or owner thereof. The information is needed for law enforcement purposes.

EFFECTIVE DATE: June 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert J. Stankey, Assistant to the Director, Office of Law Enforcement, U.S. Department of the Treasury, Room 1462, Washington, D.C. 20220, 202-566-5630.

SUPPLEMENTARY INFORMATION: The Treasury Department published a