

Issued in Fort Worth, Texas, on September 27, 1973.

NOTE.—The incorporation by reference provisions in this document were approved by the Director of the Federal Register on June 19, 1967.

A. H. THURBURN,
Acting Director,
Southwest Region.

[FR Doc.73-21456 Filed 10-9-73;8:45 am]

[Airspace Docket No. 73-EA-64]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone

On page 21796 of the FEDERAL REGISTER for August 13, 1973, the Federal Aviation Administration published a proposed regulation which would alter the New York, N.Y. (John F. Kennedy International Airport), Control Zone (38 FR 406).

Interested parties were given 30 days after publication in which to submit written data or views. No objections to the proposed regulation have been received.

In view of the foregoing, the proposed regulation is hereby adopted, effective 0901 G.m.t. December 6, 1973.

(Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Jamaica, N.Y., on September 25, 1973.

ROBERT H. STANTON,
Director, Eastern Region.

1. Amend § 71.171 of Part 71 of the Federal Aviation Regulations by deleting the description of the New York, N.Y. (John F. Kennedy International Airport) control zone and by substituting the following in lieu thereof:

Within a 5-mile radius of the center 40°-38'25" N., 73°46'41" W., of John F. Kennedy International Airport; within the area bounded by a line beginning at 40°36'16" N., 73°52'32" W., to 40°37'10" N., 73°54'55" W., to 40°42'19" N., 73°51'07" W., to 40°41'23" N., 73°48'48" W., to the point of beginning; within 1.5 miles each side of the Kennedy VORTAC 106° radial, extending from the 5-mile-radius zone to 6.5 miles east of the VORTAC; within 1.5 miles each side of the Kennedy VORTAC 207° radial, extending from the 5-mile-radius zone to 5 miles southwest of the VORTAC; within 1.5 miles each side of the Kennedy VORTAC 134° radial, extending from the 5-mile-radius zone to 5 miles southeast of the VORTAC.

[FR Doc.73-21460 Filed 10-9-73;8:45 am]

[Airspace Docket No. 73-EA-67]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone

On page 22243 of the FEDERAL REGISTER for August 17, 1973, the Federal Aviation Administration published a proposed

regulation which would alter the Newark, N.J., Control Zone (38 FR 405).

Interested parties were given 30 days after publication in which to submit written data or views. No objections to the proposed regulation have been received.

In view of the foregoing, the proposed regulation is hereby adopted, effective 0901 G.m.t. December 6, 1973.

(Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Jamaica, N.Y., on September 25, 1973.

ROBERT H. STANTON,
Director, Eastern Region.

1. Amend § 71.171 of Part 71 of the Federal Aviation Regulations by deleting the description of the Newark, N.J., control zone and by substituting the following in lieu thereof:

Within a 5-mile radius of the center, 40°-41'40" N., 74°10'02" W., of Newark International Airport, Newark, N.J., extending clockwise from a 030° bearing to a 263° bearing from the airport; within a 6-mile radius of the center of the airport, extending clockwise from a 263° bearing to a 342° bearing from the airport; within a 5.5-mile radius of the center of the airport, extending clockwise from a 342° bearing to a 030° bearing from the airport; within 2 miles each side of the Newark International Airport Runway 4L ILS localizer course, extending from the 5-mile radius to 2.5 miles northeast of the Chelsea OM and within 3 miles each side of the Kennedy VORTAC 283° radial extending from 22 miles to 29 miles northwest of the VORTAC.

[FR Doc.73-21459 Filed 10-9-73;8:45 am]

[Airspace Docket No. 73-EA-90]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone

The Federal Aviation Administration is amending section 71.171 of Part 71 of the Federal Aviation Regulations so as to alter the Ithaca, N.Y., Control Zone (38 FR 388).

Due to a change in the daily weather reporting and air carrier services of Allegheny Airlines which will reduce the time of such services by some 6½ hours, an alternation of the description of the control zone is required. However, the change being less restrictive, notice and public procedure hereon are unnecessary and the amendment may be made effective in less than 30 days.

In view of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective on October 10, 1973, as follows:

1. Amend § 71.171 of Part 71, Federal Aviation Regulations so as to amend the description of the Ithaca, N.Y., Control Zone by deleting the last sentence and substituting the following in lieu thereof:

This control zone shall be effective 0600-2130 hours, local time, Monday through Sat-

urday; 0700-2130 hours, local time Sunday. (Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Jamaica, N.Y., on September 26, 1973.

LOUIS J. CARDINALI,
Acting Director,
Eastern Region.

[FR Doc.73-21458 Filed 10-9-73;8:45 am]

[Airspace Docket No. 73-EA-60]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone and Transition Area

On page 21434 of the FEDERAL REGISTER for August 8, 1973, the Federal Aviation Administration published proposed regulations which would alter the Phillipsburg, Pa., Control Zone (38 FR 411, 3506) and Transition Area (38 FR 555, 3506, 8643).

Interested parties were given 30 days after publication in which to submit written data or views. No objections to the proposed regulations have been received.

In view of the foregoing, the proposed regulations are hereby adopted, effective 0901 G.m.t. December 6, 1973.

(Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Jamaica, N.Y., on September 26, 1973.

LOUIS J. CARDINALI,
Acting Director,
Eastern Region.

1. Amend § 71.171 of Part 71 of the Federal Aviation Regulations by deleting the description of the Phillipsburg, Pa. control zone and by substituting the following in lieu thereof:

Within a 5-mile radius of the center 40°-53'00" N., 78°05'15" W., of Mid-State Airport, Phillipsburg, Pa., extending clockwise from a 248° bearing to a 031° bearing from the airport; within a 6-mile radius of the center of the airport, extending clockwise from a 031° bearing to a 098° bearing from the airport; within a 5-mile radius of the center of the airport, extending clockwise from a 098° bearing to a 187° bearing from the airport; within a 6-mile radius of the center of the airport, extending clockwise from a 187° bearing to a 248° bearing from the airport; and within 4 miles each side of a 327° bearing from a point 40°53'09" N., 78°05'06" W., extending from said point to a point 8.5 miles northwest.

2. Amend § 71.181 of Part 71 of the Federal Aviation Regulations by deleting the description of the Phillipsburg, Pa. transition area and by substituting the following in lieu thereof:

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the center 40°53'00" N., 78°05'15" W., of Mid-State Airport, Phillipsburg, Pa., extending clockwise from a 261° bearing to a 012°

bearing from the airport; within an 8.5-mile radius of the center of the airport, extending clockwise from a 012° bearing to a 098° bearing from the airport; within a 6-mile radius of the center of the airport, extending clockwise from a 098° bearing to a 183° bearing from the airport; within a 9.5-mile radius of the center of the airport, extending clockwise from a 183° bearing to a 261° bearing from the airport; within 3.5 miles each side of the Phillipsburg VORTAC 067° radial, extending from the VORTAC to 11.5 miles northeast of the VORTAC; within 4 miles each side of the 327° bearing from a point 40°53'09" N., 78°05'06" W., extending from said point to a point 8.5 miles northwest; within 2.5 miles each side of the Phillipsburg VORTAC 330° radial, extending from the VORTAC to 6 miles northwest of the VORTAC; and within 3.5 miles each side of the Phillipsburg VORTAC 301° radial, extending from the VORTAC to 11.5 miles northwest of the VORTAC.

[FR Doc.73-21457 Filed 10-9-73;8:45 am]

[Airspace Docket No. 73-EA-63]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Transition Area

On page 21796 of the FEDERAL REGISTER for August 13, 1973, the Federal Aviation Administration published a proposed rule which would alter the Wilmington, Del., Transition Area (38 FR 601).

Interested parties were given 20 days after publication in which to submit written data or views. No objections to the proposed regulations have been received.

In view of the foregoing, the proposed regulation is hereby adopted, effective 0901 G.m.t. December 6, 1973.

(Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Jamaica, N.Y., on September 24, 1973.

ROBERT H. STANTON,
Director, Eastern Region.

1. Amend § 71.181 of Part 71, Federal Aviation Regulations so as to alter the description of the Wilmington, Delaware 700-foot floor transition area by deleting all after, "Summit Airpark Airport," and substituting therefor, "Middletown, Del.; within 2.5 miles each side of a line bearing 345° from a point in latitude 39°23'31" N., longitude 75°40'38" W., extending from said point to the 5-mile radius area centered on Summit Airpark Airport and within 3 miles each side of a 234° bearing from the Greater Wilmington, Del., ILS OM extending from the Summit Airpark Airport 5-mile radius area to 13 miles southwest of the OM."

[FR Doc.73-21461 Filed 10-9-73;8:45 am]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release No. 33-5424]

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

Summaries of Registration Statements To Be Submitted With Such Statements by the Registrants

The Securities and Exchange Commission today announced that it has adopted Rule 458, to become effective November 15, 1973. The rule was published for comment on July 24, 1973, in Securities Act Release No. 5410, and in the FEDERAL REGISTER for August 3, 1973, at 38 FR 20903. The rule requires any company filing a registration statement with the Securities and Exchange Commission other than on Form S-8 or S-12 to provide in a letter but not as part of the registration statement a one-paragraph summary for the SEC News Digest as notice of the registration filing. The Commission has considered the comments received in response to that release and now adopts the rule as set forth below.

Commission action. Pursuant to authority in section 19(a) of the Securities Act of 1933, the Securities and Exchange Commission hereby adopts a new § 230.458 under Part 230 of Chapter II of Title 17 of the Code of Federal Regulations, reading as follows:

§ 230.458 Brief descriptive summary of registration statement.

(a) A letter, addressed to the Commission's Office of Public Information and containing the information described below, shall be submitted by registrant as part of the materials accompanying the initial filing with the Commission of any registration statement on any form other than Form S-8 (17 CFR 239.16b) or S-12 (17 CFR 239.19). No summary is required for pre- and post-effective amendments. Such letter shall contain only a summary of the offering to which the registration statement relates, which summary shall include only the following items of information, where applicable, in the following order:

- (1) The form on which the registration statement is filed;
- (2) The name and address of the issuer of the security;
- (3) The full title of the security or securities and the amount being offered;
- (4) The price of the security, if known at the time of the offering;
- (5) The name and address of the managing underwriter(s), if any; or, if the security is to be offered at competitive bidding, so state;
- (6) In the case of a rights offering, the class of securities the holders of which will be entitled to subscribe, the subscription ratio, the record date if known, and the price of the security if known at the time of the offering, or any of the foregoing;

(7) In the case of an exchange or tender offer, the name of the issuer and the title of the securities to be surrendered in exchange for the securities to be offered and the basis on which the exchange may be made;

(8) A statement of the amount of the offering, if any, to be made by selling security holders;

(9) A brief indication of the primary business of the issuer.

(b) A letter furnished in compliance with this Section shall be deemed not to be "filed" with the Commission and not to be a part of the registration statement. For purposes of section 5 of the Act only, information furnished pursuant to this section and published in the News Digest or any similar publication of the Commission shall be deemed not to constitute an offer when so published.

(c) **Instruction.** The information should be presented in a form similar to the examples which follow, as appropriate:

(1) **General.** (i) ABC, INC., 3700 50th Avenue, Bladensburg, Md. 20710—\$1,500,000 of convertible subordinated debentures and 150,000 shares of common stock, to be offered for sale in units, each consisting of a \$250 debenture and 25 shares, and at \$500 per unit through underwriters headed by Blank & Co., Inc., 1720 F St. NW., Washington, D.C. 20006. The company is a commercial printer, engaged in web offset lithography and book binding.

(2) **Secondary offer.** (i) MNO Company, 50 Detroit Avenue, Lakewood, Ohio 44107—72,000 shares of common stock, which may be offered for sale (or pledged) from time to time by certain shareholders at prices current at the time of sale. MNO is an automotive parts manufacturer.

(3) **Exchange offer.** (i) PQR, Inc., 500 Second Avenue, Cedar Rapids, Iowa 52401—168,000 shares of common stock. It is proposed to offer these shares in exchange for the outstanding common shares of Blank National Bank, Waterloo, Iowa, at the rate of seven shares for each Bank share. Also included in this statement are 160,000 shares of common stock, which may be issued in connection with future acquisitions of other businesses of properties. PQR is a bank holding company, which controls four banks.

(4) **Rights offer.** (i) VWX, Inc., 1 Florida Avenue, Tampa, Fla. 33602—409,249 shares of common stock. It is proposed to offer these shares for subscription by common stockholders of record June 15, at the rate of one share for each five shares held, and at \$25 per share. Black & Co., Inc., 10 Chase Manhattan Plaza, New York, is principal underwriter. The company is a bank holding company with four banking subsidiaries.

(5) **Miscellaneous.** (i) YZ Enterprises, Inc., 660 Wilshire Blvd., Los Angeles, California 90057—732,812 shares of common stock. Of these shares, 276,719 were issued in connection with acquisitions made by the company; 15,000 are issuable upon exercise of options granted to Gray & Co.; 51,122 are reserved for is-

suance upon conversion of 5 percent convertible second mortgage bonds, due 1981; 119,700 were issued in private placements in 1969; and 270,271 are reserved for issuance upon conversion of outstanding 7 percent convertible subordinated guaranteed bonds, due 1990, of YZ International N.V., wholly owned subsidiary of the company. The company operates 14 general hospitals.

By the Commission.

(Sec. 19(a), 48 Stat. 85, sec. 209, 48 Stat. 908, 15 U.S.C. 775(a).)

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 20, 1973.

[FR Doc. 73-21441 Filed 10-9-73; 8:45 am]

Title 21—Food and Drugs

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

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 18—MILK AND CREAM

In the matter of revising existing standards and establishing new identity standards for milk and cream (21 CFR Part 18):

A notice of proposed rulemaking in the above-identified matter published on the initiative of the Commissioner of Food and Drugs in the FEDERAL REGISTER of September 9, 1972 (37 FR 18392) provided for the filing of comments within 60 days following its publication date. This was subsequently extended to February 6, 1973, by notice published in the FEDERAL REGISTER on November 2, 1972 (37 FR 23363), and was again extended to July 1, 1973, by notice published in the FEDERAL REGISTER on February 13, 1973 (38 FR 4347).

During the extended comment period more than 650 comments were received from industry, consumer and professional groups, trade associations, and individuals.

1. The requirement that fluid milk products for consumer use be pasteurized was objected to by some, and supported by others. Those who objected to the requirement contended that raw certified milk is a safe product, and that raw milk is superior in flavor.

While raw milk produced under carefully controlled conditions is relatively safe, pasteurization assures the destruction of pathogenic bacteria that may be present. The Commissioner concludes that it is reasonable to require that fluid milk products for consumer use moving in interstate commerce be pasteurized. This decision does not conflict with the right of individual states to authorize the intrastate distribution of raw milk to consumers.

2. The requirement that all milk, lowfat milk, and skim milk bottled for beverage use contain 400 International Units per quart of vitamin D was objected to, and it was contended that consumers should have a choice between milk with and without added vitamin D.

The need for vitamin D in human nutrition and the importance of main-

taining a daily intake sufficient to protect infants and growing children from developing rickets is well established. Industry sources state that at present approximately 98 percent of all homogenized milk sold in this country contains added vitamin D, and that in some market areas, vitamin D milk is the only kind available. There is the possibility that some firms, in order to evade the nutritional labeling required by 21 CFR 1.17 for foods containing added vitamins, will discontinue the practice of adding vitamin D to milk. The Commissioner concludes that vitamin D addition to milk, lowfat milk, and skim milk for beverage use should remain optional, in order to provide for the small number of consumers who want to avoid added vitamin D. However, the Commissioner will observe the market, and in the event that the percentage of vitamin D milk in relation to all milk marketed declines, will give consideration to amendment of the standards to make vitamin D addition to fluid milk products mandatory. In addition, the use of vitamin D in milk without label declaration that vitamin D has been added will cause the product to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act.

3. Those who opposed the mandatory addition of vitamin D to fluid milk products also objected to the proposed requirement for mandatory addition of vitamin A to lowfat milk and skim milk, and argued the right of consumers to choose between products with and without added vitamin A.

Dairy products are an important source of vitamin A, but the vitamin A activity is removed with the milkfat when milk is separated into cream and skim milk. Consequently, lowfat milk is reduced in vitamin A content, and skim milk contains only vestigial amounts of vitamin A. Those who make a practice of substituting lowfat or fat free dairy products for conventional dairy products may have diets deficient in vitamin A unless supplementation is undertaken. The Commissioner concludes that to require the restoration of lowfat milk and skim milk to the vitamin A level found in whole milk from cows on summer pasture is reasonable, and the order set forth below affirms this requirement.

4. The addition of nonfat milk solids to lowfat milk and skim milk increases the viscosity and opacity of these products, and results in improved palatability, appearance, and nutritive value. The proposed identity standards for fluid milk products, while permitting this practice, did not list for optional use other viscosity-increasing additives such as lactose, emulsifiers, and stabilizers. Comments from 289 consumers supported the ban on addition of lactose to fluid milk products. Comments from State regulatory officials favored optional use of emulsifiers and stabilizers, while most industry comments received asked that provision be made for use of lactose as well as emulsifiers and stabilizers. Industry comments stated that nonfat dry milk is now in short supply in this country and has

increased sharply in price, and that these increases in ingredient cost tend to drive up the prices consumers must pay for fluid milk products containing added nonfat milk solids.

The use of viscosity-increasing additives to make a fluid milk product having a lesser nonfat milk solids content resemble the more expensive and nutritious high nonfat milk solids product appears to conflict with the provision of section 402(b)(4) of the Federal Food, Drug, and Cosmetic Act prohibiting addition of substances to make a food "appear better or of greater value than it is". The use of lactose to increase the viscosity of lowfat milk and skim milk affects the nutritive value of these foods by increasing the carbohydrate content and the calorie to protein ratio, changes that are undesirable for those on calorie restricted diets. Fluid milk products with added lactose should also be avoided by those individuals whose bodies produce inadequate amounts of the enzyme lactase and therefore can tolerate only limited amounts of lactose.

The Commissioner concludes that viscosity-increasing ingredients derived from milk should be permitted in fluid milk products, but only on condition that they do not serve to adulterate the nutritive value of the food solids present in the foods. The order set forth below provides that viscosity-increasing ingredients used shall contain protein sufficient in quantity and quality that the ratio of protein to total nonfat solids in the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients. The order also permits use of limited amounts of emulsifiers and stabilizers, but only in conjunction with addition of milk derived solids.

5. Several individuals and milk producer groups advocated higher minimum milkfat and milk solids not fat levels for whole milk than were proposed, on grounds that this would improve the flavor of the products. An increase in the minimum nonfat milk solids content of milk, lowfat milk, and skim milk was also suggested either as a mandatory requirement or as an option, with use of the term "fortified" to designate those products having a higher nonfat milk solids content.

The average milkfat content of milk produced by cows in the United States in 1972 was 3.68 percent, slightly higher than the 3.25 percent minimum specified by the proposed identity standard for milk. Similarly, the estimated average milk solids not fat level of 8.61 percent is higher than the 8.25 percent minimum proposed. However, to set the required minimums for milkfat and milk solids not fat at or near these average figures would mean that in approximately half of all cases the production from an individual cow would not meet the minimum compositional requirements, and therefore would not be "milk" as defined by the identity standard. While the Commissioner is aware of the merits of fluid milk products having increased milk solids content, he is of the opinion that

the minimums proposed bear a reasonable relationship to the composition of milk as it comes from the cow; and that an increase of the milkfat content of milk above 3.25 percent, and of the milk solids not fat level above 8.25 percent, is a matter of quality rather than identity. Nutrition labeling on most milk containers will set forth the content of milkfat, carbohydrates, and protein, giving consumers the information needed to make milk solids content comparisons between different brands of milk products. Therefore, the order set forth below includes the milkfat and milk solids not fat minimums specified in the proposal, but also provides for protein fortified lowfat milk and skim milk containing a minimum of 10 percent nonfat solids.

6. The proposed standards do not provide for fortification of fluid milk products with vitamins and minerals, except for addition of controlled amounts of vitamins A and D. Some comments suggested that provision should be made for the marketing of multivitamin and multimineral fortified fluid milk products.

The Commissioner is of the opinion that available information does not substantiate the need for multivitamin and multimineral fortified fluid milk products. Vitamin D milk is a good source of most vitamins and minerals without further fortification. While addition of iron would make milk a more complete food, further work is necessary to develop a method of iron addition that does not adversely affect the flavor of milk. Consideration will be given to optional addition of iron or other nutrients when it can be shown that fluid milk products are practical as vehicles for including such nutrients in the diet.

7. A new process has been used in this country to produce "sterilized" cream which, though not truly sterile, will keep in its intact package for at least 6 weeks in refrigerated storage. The process employs a heat treatment utilizing temperatures higher than are required for pasteurization, together with special protective packaging and aseptic filling methods. The notice published in the *FEDERAL REGISTER* on September 9, 1972 (37 FR 18392) proposed that the term "special process" be used to label such cream and other extended shelf life fluid milk products, but invited comments as to other names for the products that would be more appropriate. Several comments suggested other names, and 168 comments from consumers expressed concern about the safety of these longer keeping fluid dairy products, or criticized their flavor.

The Commissioner concludes that available information supports the safety and usefulness of the extended shelf life fluid dairy products, and the order set forth below makes provision for them, but specifies the label designation "ultra-pasteurized" rather than "special process" for naming such products.

8. Concern was shown in several comments that flavored fluid milk products, which were not provided for by the proposed standards, would therefore not be permitted in interstate commerce. Since

flavored milks, such as chocolate milk, do not purport to be and are not represented as milk, their distribution as nonstandardized foods could be continued after the establishment of an identity standard for milk. However, the Commissioner concludes that it would be reasonable to include provision for flavored fluid milk products while promulgating identity standards for milk, lowfat milk, and skim milk. The order set forth below provides for such addition of characterizing flavoring, with appropriate label declaration as specified in 21 CFR 1.12.

9. An association representing the evaporated milk manufacturers requested that the minimum fat level of this product be lowered from 7.9 percent to 7.5 percent by weight, and that a corresponding change from 25.9 to 25.5 percent be made in the minimum total milk solids requirement of the food. The evaporated milk identity standard established the composition of the food so that the reconstituted product (prepared by addition of an equal volume of water to evaporated milk) closely approximated the composition of cows' milk. Since the time the standard was promulgated, the average fat content of cows' milk in this country has decreased because the number of cattle from those breeds that produce milk having a high fat content has declined. The evaporated milk manufacturers are therefore seeking a downward adjustment in the fat content of their product to more closely approximate the current composition of cows' milk.

The Commissioner concludes that a reduction in the minimum fat content of evaporated milk is reasonable in view of the compositional changes in cows' milk that have occurred, and the requested changes are incorporated in the order set forth below.

10. One comment objected to the reference by the proposal to certain Association of Official Analytical Chemists (AOAC) methods to the exclusion of other methods that could be used for determining the same attributes. Two other comments expressed a preference for the Babcock method, rather than the Roesse-Gottlieb method specified by the proposal, for determining the milkfat content of fluid milk products.

The Commissioner is of the opinion that it is necessary for all concerned to know what analytical methods will be used to determine compliance with the composition requirements of the standards, particularly when several methods are available. The designation of a reference method does not preclude the use of other available methods for regulatory purposes by State and local agencies, for quality control work, or as screening tests.

11. A number of comments opposed provisions of the proposal that would result in name changes or other changes in the labeling of fluid milk products. It was pointed out that the cost to industry for redesigning all labels will likely be passed on to consumers. In particular, the proposed name "milk-vitamin D added" to replace the established name "vitamin D milk" was objected to.

Changes in the labeling of most fluid milk products and many other foods are required by the nutrition labeling order and other orders published in three issues of the *FEDERAL REGISTER* on January 19, 1973 (38 FR 2124), March 14, 1973 (38 FR 6951), and August 2, 1973 (38 FR 20702). These orders, and the order set forth below, all have a common effective date, so that labels may be redesigned just once to comply with the new regulations. The Commissioner concludes that all desirable labeling changes for fluid milk products should be made at this time, and the order set forth below does retain most of the labeling requirements of the proposal. However, the Commissioner agrees that the name "vitamin D milk" is familiar to consumers, and the order permits the continuation of this name.

12. Some comments suggested the name "nonfat milk" as an option for "skim milk", and cited general use of the name "nonfat dry milk" as a precedent.

The Commissioner concurs with this suggestion, and the order set forth below provides for the two alternative names.

The Commissioner has carefully reviewed and considered all comments received and other relevant information, and to the extent that they are not encompassed within the above discussion or modifications made in the regulation they are rejected. Minor changes have been made in the labeling requirements proposed for fluid milks and creams to bring about greater consistency in the labeling of these two classes of dairy products. A proposed amendment of 21 CFR 10.1 to define the term "safe and suitable", which is used in the following order, was published in the *FEDERAL REGISTER* of April 26, 1973 (38 FR 10274).

Several milk industry groups have requested an extension of the December 31, 1973, requirement which provides that all labeling ordered after this date comply with the provisions of nutritional labeling (21 CFR 1.17). These industry groups have initiated comprehensive studies to develop nutritional data on milk, lowfat milk, skim milk and other dairy products for use in nutritional labeling. Available information indicates that these studies will not be completed in time to permit manufacturers to develop labels in order to meet the December 31, 1973, deadline. The Commissioner of Food and Drugs considers the request for extension reasonable and has extended this date to coincide with the December 31, 1974, date when labeling used on products must conform to the provisions of 21 CFR 1.17.

Accordingly, having considered the comments received and other relevant information, the Commissioner concludes that it will promote honesty and fair dealing in the interest of consumers to adopt the modified proposal, as set forth below.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055-1056; as amended 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371) and under authority

delegated to the Commissioner (21 CFR 2.120): *It is ordered*, that Part 18 be revised to read as follows:

Sec.	Definitions.
18.1	Milk; identity.
18.2	Lowfat milk; identity.
18.10	Skim milk; identity.
18.20	Half-and-half; identity.
18.30	Light cream; identity.
18.501	Light whipping cream; identity.
18.511	Heavy cream; identity.
18.520	Evaporated milk; identity.
18.525	Concentrated milk; identity.
18.530	Sweetened condensed milk; identity.
18.540	Nonfat dry milk; identity.
18.545	Nonfat dry milk fortified with vitamins A and D; identity.

AUTHORITY.—Secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).

§ 18.1 Definitions.

(a) "Cream" means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) "Pasteurized" when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph 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
145°F ¹ —————	30 minutes
161°F ¹ —————	15 seconds
191°F —————	1 second
204°F —————	0.05 second
212°F —————	0.01 second

¹ If the dairy ingredient has a fat content of 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F.

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

§ 18.2 Milk; identity.

(a) **Description.** Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, and shall contain not less than 8½ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) **Vitamin addition (Optional).** (1) If added, vitamin A shall be present in such quantity that each quart of the

food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

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

(1) Carriers for vitamins A and D.
(2) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

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

(ii) Natural and artificial food flavorings.

(d) **Methods of analysis.** Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.²

(1) Milk fat content—"Fat, Roesse-Gottlieb Method—Official Final Action," section 16.052.³

(2) Milk solids not fat content—Calculated by subtracting the milk fat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.³

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.³

(e) **Nomenclature.** The name of the food is "milk". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany 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:

(i) If vitamins are added, the phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamin A and D" or "vitamins A and D added", as is appropriate. The word "vitamin" may be abbreviated "vit".

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) **Label declaration.** When used in the food, each of the ingredients specified in paragraphs (b) and (c) (2) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.10 Lowfat milk; identity.

(a) **Description.** Lowfat milk is milk from which sufficient milkfat has been removed to produce a food having, within

limits of good manufacturing practice, one of the following milkfat contents: ½, 1, 1½, or 2 percent. Lowfat milk is pasteurized or ultra-pasteurized, contains added vitamin A as prescribed by paragraph (b) of this section, and contains not less than 8¼ percent milk solids not fat. Lowfat milk may be homogenized.

(b) **Vitamin addition.** (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

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

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c) (2) of this section are used, emulsifiers, stabilizers, or both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

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

(ii) Natural and artificial food flavorings.

(d) **Methods of analysis.** Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.²

(1) Milkfat content—"Fat, Roesse-Gottlieb Method—Official Final Action," section 16.052.³

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.³

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.³

(e) **Nomenclature.** The name of the food is "Lowfat milk". The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany 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:

See footnote at end of document.

(i) The phrase "____% milkfat", the blank to be filled in with the fraction $\frac{1}{2}$, or multiple thereof, to indicate the actual fat content of the food.

(ii) The phrase "vitamin A" or "vitamin A added", or, if vitamin D is added, the phrase "vitamin A and D added". The word "vitamin" may be abbreviated "vit."

(iii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(iv) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk derived nonfat solids.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) **Label declaration.** When ingredients are used in the food as specified in paragraphs (b) (2) and (c) (2), (3), and (4) of this section, such ingredients shall be declared on the label as required by the applicable sections of Part 1 of this chapter except that concentrated skim milk and nonfat dry milk may be declared as "nonfat milk solids".

§ 18.20 Skim milk; identity.

(a) **Description.** Skim milk is milk from which sufficient milkfat has been removed to reduce its milkfat content to less than 0.5 percent. Skim milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, shall contain added vitamin A as prescribed by paragraph (b) of this section, and shall contain not less than 8½ percent milk solids not fat. Skim milk may be homogenized.

(b) **Vitamin addition.** (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

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

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c) (2) of this section are used, emulsifiers, stabilizers, or a combination of both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

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

(ii) Natural and artificial food flavoring.

(d) **Methods of analysis.** Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.

(1) Milkfat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.

(e) **Nomenclature.** The name of the food is "Skim milk" or alternatively "Nonfat milk". The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany 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:

(i) The phrase "vitamin A" or "vitamin A added", or, if vitamin D is added, the phrase "vitamin A and D" or "vitamins A and D added". The word "vitamin" may be abbreviated "vit."

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(iii) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk derived nonfat solids.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) **Label declaration.** When used in the food, each of the ingredients specified in paragraphs (b) (2) and (c) (2), (3), and (4) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.30 Half-and-half; identity.

(a) **Description.** Half-and-half is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milkfat. It is pasteurized or ultrapasteurized, and may be homogenized.

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

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

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

(ii) Natural and artificial food flavoring.

(c) **Methods of analysis.** The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action."

(d) **Nomenclature.** The name of the food is "Half-and-half". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany 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:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavor ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) **Label declaration.** When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.501 Light cream; identity.

(a) **Description.** Light cream is cream which contains not less than 18 percent but less than 30 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

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

(1) Stabilizers.

(2) Emulsifiers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

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

(ii) Natural and artificial food flavoring.

(c) **Methods of analysis.** The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action."

(d) **Nomenclature.** The name of the food is "Light cream", or alternatively "Coffee cream" or "Table cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less

See footnote at end of document.

than one-half the height of the letters used in such name:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.511 Light whipping cream; identity.

(a) *Description.* Light whipping cream is cream which contains not less than 30 percent but less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

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

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

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

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roesse-Gottlieb Method—Official Final Action."

(d) *Nomenclature.* The name of the food is "Light whipping cream" or alternatively "Whipping cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany 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:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by

See footnote at end of document.

the applicable sections of Part 1 of this chapter.

§ 18.515 Heavy cream; identity.

(a) *Description.* Heavy cream is cream which contains not less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

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

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

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

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roesse-Gottlieb Method—Official Final Action."

(d) *Nomenclature.* The name of the food is "Heavy cream" or alternatively "Heavy whipping cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter. The following terms shall accompany 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:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.520 Evaporated milk; identity.

(a) *Description.* Evaporated milk is the liquid food obtained by the partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. 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 Inter-

national Units thereof within limits of good manufacturing 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 § 121.1137 of this chapter) as a solubilizing agent.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Total milk solids—"Total Solids—Official Final Action," section 16.127.

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 39.149-39.162.

(e) *Nomenclature.* The name of the food is "Evaporated milk". The phrase "vitamin D" or "vitamin D added", or "vitamin 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:

(f) *Label declaration.* When used in the food, each of the ingredients specified in paragraphs (b) (2) and (c) (2) and (3) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.525 Concentrated milk; identity.

(a) *Description.* Concentrated milk is the liquid food obtained by partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. It is pasteurized, but is not processed by heat so as to prevent spoilage. It may be homogenized.

(b) *Vitamin addition (Optional).* If added, 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.

(c) *Optional ingredients.* Safe and suitable carriers may be used for vitamin D.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Total milk solids—"Total Solids—Official Final Action," section 16.127.

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 39.149-39.162.

(e) *Nomenclature.* The name of the food is "Concentrated milk" or alternatively "Condensed milk". If the food contains added vitamin D, the phrase "vitamin D" or "vitamin D added" shall accompany 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 word "homogenized" may appear on the label if the food has been homogenized.

(f) *Label declaration.* When used in the food, the optional ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.530 Sweetened condensed milk; identity.

(a) *Description.* Sweetened condensed milk is the food obtained by the partial removal of water only from a mixture of milk and safe and suitable nutritive sweetener. The finished food contains not less than 8.5 percent by weight of milkfat, and not less than 28 percent by weight of total milk solids. The quantity of nutritive sweetener used is sufficient to prevent spoilage. The food is pasteurized, and may be homogenized.

(b) *Method of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.142, under "Fat—Official Final Action."²

(c) *Nomenclature.* The name of the food is "Sweetened condensed milk". The word "homogenized" may appear on the label if the food has been homogenized.

(d) *Label declaration.* The optional sweetener used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.540 Nonfat dry milk; identity.

(a) *Description.* Nonfat dry milk is the product obtained by removal of water only from pasteurized skim milk. It contains not more than 5 percent by weight of moisture, and not more than 1½ percent by weight of milkfat unless otherwise indicated.

(b) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.²

(1) *Moisture content.*—"Moisture—Official Final Action," section 16.149.²

(2) *Milkfat content.*—"Fat in Dried Milk—Official Final Action," sections 16.156–16.157.²

(c) *Nomenclature.* The name of the food is "Nonfat dry milk". If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement "Contains ----% milkfat", the blank to be filled in with the percentage to the nearest one-tenth of 1 percent of fat contained, within limits of good manufacturing practice.

§ 18.545 Nonfat dry milk fortified with vitamins A and D; identity.

(a) *Description.* Nonfat dry milk fortified with vitamins A and D conforms to the standard of identity for nonfat

dry milk, except that vitamins A and D are added as prescribed by paragraph (b) of this section.

(b) *Vitamin addition.* (1) Vitamin A is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 2000 International Units thereof.

(2) Vitamin D is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 400 International Units thereof.

(3) The requirements of this paragraph will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are present to insure that the required levels of vitamins are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Optional ingredients.* Safe and suitable carriers for vitamins A and D.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.²

(1) *Moisture content.*—"Moisture—Official Final Action," section 16.149.²

(2) *Milkfat content.*—"Fat in Dried Milk—Official Final Action," sections 16.156–16.157.²

(c) *Nomenclature.* The name of the food is "Nonfat dry milk fortified with vitamins A and D". If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement "Contains ----% milkfat", the blank to be filled in to the nearest one-tenth of 1 percent with the percentage of fat contained, within limits of good manufacturing practice.

Any person who will be adversely affected by the foregoing order may at any time on or before November 9, 1973, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-88, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order 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. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date.—Unless stayed by the filing of proper objections, compliance with this order, which shall include any labeling changes required, may begin on December 10, 1973, and all labeling used for products shipped in interstate commerce after December 31, 1974, shall comply with these regulations.

(Sec. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).)

Dated September 28, 1973.

SAM D. FINE,
Associate Commissioner for
Compliance.

NOTE.—Incorporation by reference provisions approved by the Director of the Federal Register March 26, 1973.

[FR Doc. 73-21485 Filed 10-9-73; 8:45 am]

**SUBCHAPTER B—FOOD AND FOOD PRODUCTS
PART 26—NUTRITIVE SWEETENERS**

Correction

In FR Doc. 73-19632 appearing at page 25985 in the issue of Monday, September 17, 1973, make the following changes in the preamble:

1. In the paragraph following paragraph 4, the standard number in the 14th line reading "CAC/RS 10-2969" should read "CAC/RS 10-1969".

2. The 18th line of that paragraph reading "standard CAC/RS 10-1969 be similarly", should read "standards in whole or in part do not pro-".

3. In paragraph 6 the word "and" in the 5th line from the bottom should read "for".

**SUBCHAPTER C—DRUGS
PART 151b—BACITRACIN**

Zinc Bacitracin-Neomycin Sulfate-Polymyxin B Sulfate Ophthalmic Ointment

The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act, as amended, with respect to providing for the certification of an ophthalmic ointment containing 500 units zinc bacitracin, 3.5 milligrams neomycin sulfate, and 10,000 units polymyxin B sulfate.

The Commissioner has concluded that the data supplied by the manufacturer concerning the subject antibiotic drug is adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations published in the FEDERAL REGISTER of July 24, 1973 (38 FR 19817) should be amended to provide for the certification of this drug.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and under authority delegated to the Commissioner (21 CFR 2.120), Part 151b is amended in § 151b.22 by revising paragraph (a) (1) to read as follows:

§ 151b.22 Zinc bacitracin—neomycin sulfate—polymyxin B sulfate ophthalmic ointment.

(a) *Requirements for certification.* (1) *Standards of identity, strength, quality, and purity.* Zinc bacitracin—neomycin sulfate—polymyxin B sulfate ophthalmic ointment is zinc bacitracin, neomycin sulfate, and polymyxin B sulfate

²Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044.