General

area of the eye, exempts the color from certification, and removes ferric ferrocyanide (iron blue) from the provisional listing.

DATE: Effective date confirmed: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of November 21, 1978 (43 FR 54235) added new §§ 73.1299 and 73.2299 (21 CFR 73.1299 and 73.2299) to provide for the safe use of ferric ferrocyanide (iron blue) as a color additive for use in externally applied drugs and cosmetics, including those intended for use in the area of the eye. The regulation also amended § 81.1 *Provisional listing of color additives* (21 CFR 81.1) by deleting the entry in paragraph (g) for ferric ferrocyanide (iron blue) and amended § 81.27 *Conditions of provisional listing of additives* (21 CFR 81.27) by deleting from paragraph (c) the requirements for ferrocyanide (iron blue).

Pursuant to the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376 (b), (c), and (d)) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of November 21, 1978. Accordingly, the amendments promulgated thereby became effective on December 22, 1978.

Dated: March 8, 1979.

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

[FR Doc. 79-7642 Filed 3-15-79; 8:45 am]

[4110-03-M]

[Docket No. 75N-0107]

FOODS FOR SPECIAL DIETARY USE

Vitamin and Mineral Products; Revocation of Regulations

AGENCY: Food and Drug Administration.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA) revokes regulations the United States Court of Appeals for the Second Circuit has ruled are invalid. The regulations had established definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

L. Robert Lake, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1254.

SUPPLEMENTARY INFORMATION: Regulations establishing definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals were first issued in 1973 after a lengthy administrative hearing. The regulations defined five types of preparations and prescribed maximum and minimum potencies for ingredients. These potencies were stated in terms of a new unit of measurement, the U.S. Recommended Daily Allowances (U.S. RDA) that were derived from the Recommended Dietary Allowances published by the Food and Nutrition Board of the National Academy of Sciences/National Research Council. In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for that nutrient; the maximum potency, at 150 percent of the U.S. RDA. The 1973 regulations were challenged by fifteen petitioners. In a lengthy opinion, the United States Court of Appeals for the Second Circuit "broadly sustain[ed] the regulations" but remanded them to the agency for further action. *National Nutritional Foods Ass'n* v. *FDA*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975).

While FDA was in the process of implementing the Court's remand directions, Congress enacted new legislation (Pub. L. 94-278, Title V, sections 501-502, 90 Stat. 410-413; April 22, 1976) restricting FDA's authority to limit the maximum potency of vitamins and minerals and ingredient composition in dietary supplements offered for use by adults (other than pregnant or lactating women) and recognized as safe. Codified in part, these amendments became section 411 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350).

In the FEDERAL REGISTER of October 19, 1976 (41 FR 46156), FDA promulgated regulations (21 CFR 125.1, 125.2, 125.3, and 80.1 (recodified as 21 CFR 105.3, 105.60, 105.77, and 105.85, respectively, in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302))) to comply with both the Court's remand directions and the 1976 vitamin and mineral amendments. In effect, the agency retained the standard of identity promulgated in 1973, amended it in accordance with the Court's instructions, and incorporated an exemption from the limitations on maximum potency and ingredient composition in dietary supplements offered for use by most adults to comply with the 1976 legislation.

Subsequently, a petition was submitted by National Nutritional Foods Association (NNFA) asking the agency to reconsider the procedural propriety of amending the regulations to comply with 1976 amendments without notice and comment. In the FEDERAL REGISTER of April 19, 1977 (42 FR 20292), FDA denied the petition, noting that the 1976 amendments contained a provision that the dietary supplement regulations be revised in accordance with 5 U.S.C. 553 to conform to the legislation; that 5 U.S.C. 553 contains a good cause exemption from notice and public procedures; and that the changes in the dietary supplement regulations to conform them to requirements of the 1976 amendments satisfied the good cause exemption.

On appeal, the Second Circuit held that the good cause exemption in 5 U.S.C. 553 is to be narrowly construed, and that the dietary supplement regulations do not qualify for the exemption and must be republished for comment. In addition, the court held, *inter alia*, that vitamins and minerals that are not generally recognized as safe are food additives under the act, and that the agency has authority to retain the minimum potency requirements for dietary supplements. *National Nutritional Foods Ass'n* v. *Kennedy*, 572 F. 2d 377 (2d Cir. 1978).

Copies of the judicial decisions cited above have been placed on file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday.

Under the decision by the Court of Appeals, the Commissioner of Food and Drugs hereby orders that 21 CFR 105.3, 105.60, and 105.85 be revoked or revised. Those portions of the regulations which were to have been superseded by amendment of Part 105 are hereby reinstated. Accordingly, Parts 101, 105, and 201 are amended as follows:

PART 101—FOOD LABELING

1. In part 101:

a. By revising § 101.2(c)(1)(iii)(*a*), (2)(iii)(*a*), and (3)(ii)(*a*) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(c) * * *

(1) * * *

(iii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(2) * * *
(iii) * * *
(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(3) * * *
(ii) * * *
(a) Nutrition labeling in accordance with § 101.9.

* * * * *

b. Section 101.9 is amended by revising paragraphs (a)(2) and (h)(1)(i) and (2) to read as follows:

§ 101.9 Nutrition labeling of food.

(a) * * *

(2) If any vitamin and/or mineral is added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age, as specified in paragraph (c)(7)(iv) of this section, of one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this section.

* * * * *

(h) * * *

(1)(i) Except where expressly covered by § 105.65 of this chapter, infant, baby, and junior-type food promoted for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section.

* * * * *

(2) Dietary supplements are exempted, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section.

PARTS 105—FOODS FOR SPECIAL DIETARY USE

2. In Part 105:

a. Section 105.3 is amended by revising paragraph (a)(1), by deleting paragraphs (b) and (c), by revising paragraphs (d) and (e), and by deleting paragraphs (f) and (g) as follows:

§ 105.3 Definitions and interpretations.

* * * * *

(a)(1) The term "special dietary uses", as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

* * * * *

(b) and (c) [Reserved]

(d) If a food purports to be or is represented for special dietary use by man by reason of the presence of any constituent which is not utilized in normal metabolism, the label shall bear a statement of the percent by weight of such constituent, and, in juxtaposition with the name of such constituent, the word "nonnutritive". If such constituent is fibrous plant matter, it shall be considered to be crude fiber and its percent expressed as such. But if such constituent is saccharin or a saccharin salt, the label shall bear, in lieu of such statement and word, the statement "Contains saccharin (or saccharin salt, as the case may be), a nonnutritive, artifical sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin or saccharin salt in such food. The provisions of this section shall not be construed as authorizing the use of saccharin or its salts in any food other than one for use by persons who must restrict their intake of carbohydrates, or as relieving any food from compliance with any requirement of section 402(b) or (d), 403(g), or other provisions of the act.

(e) For the purposes of the regulations in this part, the terms "infant," "child," and "adult" mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§§ 105.60, 105.77, and 105.85 [Revoked]

b. By revoking § 105.60 *Restrictions, placement, false or misleading representations*, § 105.77 *Vitamins and minerals*, and § 105.85 *Dietary supplements of vitamins and minerals.*

PART 201—LABELING

§ 201.19 [Amended]

3. In Part 201, § 201.19 is amended by changing "§ 105.3(d)" to read "§ 105.3(e)."

Because this order is a ministerial act revoking regulations already ruled by the Court of Appeals to be invalid, and because it relieves a restriction and there is no useful purpose in postponing the effective date, the Commissioner concludes, under the Administrative Procedure Act (5 U.S.C. 553(b)(B) and (d)(1) and (3)), that notice and public procedure and delayed effective date are unnecessary.

Executive Order 12044 on improving government regulations requires the agency to consider economic impacts in the development of regulations. Because this action is being taken to revoke regulations which the Court of Appeals has already invalidated, no assessment of its economic impact is being made at this time. No economic impacts are expected to occur from the revocation since no new requirements are imposed at this time. The economic impact of vitamin and mineral supplement standards and labeling regulations will be evaluated in the course of reissuing these regulations through the normal rulemaking procedure.

Effective date. This order is effective March 15, 1979.

Dated: March 12, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7982 Filed 3-15-79; 8:45 am]

[4110-03-M]

Subchapter D—Drugs for Human Use

[Docket No. 78N-0341]

PART 448—PEPTIDE ANTIBIOTIC DRUGS

Combination Otic Solutions and Suspensions; Postponement of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document postpones the effective date of a final rule that revises provisions for certification or release of certain combination otic products. The effective date is postponed to allow time for completion of review of the requests for a hearing.