902(a)(5), 1382e, 1382g, and 1383); sec. 212, Public Law 93–66, 87 Stat. 155 (42 U.S.C. 1382 note); sec. 8(a), (b)(1)–(b)(3), Public Law 93–233, 87 Stat. 956 (7 U.S.C. 612c note, 1431 note and 42 U.S.C. 1382e note); secs. 1(a)–(c) and 2(a), 2(b)(1), 2(b)(2), Public Law 93–335, 88 Stat. 291 (42 U.S.C. 1382 note, 1382e note).

7. Section 416.2096 is amended by adding a new paragraph (c)(6) to read as follows:

§ 416.2096 Basic pass-along rules.

* * * * *

(c) * * *

(6) To determine whether a State's expenditures for supplementary payments in the 12-month period beginning on the effective date of any increase in the level of SSI benefits are not less than the State's expenditures for the payments in the preceding 12-month period, in computing the State's expenditures, we disregard, pursuant to a one-time election of the State, all expenditures by the State for the retroactive supplementary payments that are required to be made under the *Sullivan* v. *Zebley*, 493 U.S. 521 (1990) class action.

* * * * *

[FR Doc. 97–14615 Filed 6–5–97; 8:45 am]

BILLING CODE 4190–29–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 91F–0160]

Food Additives Permitted For Direct Addition to Food For Human Consumption; Polydextrose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polydextrose as a formulation aid in film coatings applied to vitamin and mineral supplement tablets. This action is in response to a petition filed by Scientific Services, Colorcon (Colorcon).

DATES: Effective June 6, 1997; written objections and requests for a hearing by July 7, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3107.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 31, 1991 (56 FR 24821), FDA announced that a food additive petition (FAP 1A4258) had been filed by Colorcon, 415 Moyer Blvd., West Point, PA 19486, proposing that § 172.841 *Polydextrose* (21 CFR 172.841) be amended to provide for the safe use of polydextrose as a formulation aid (film former/adhesion promoter) in film coatings applied to vitamin and mineral supplement tablets.

Film coatings are applied to tableted food supplements to mask taste and to facilitate both swallowing and identification. In the petition, data were provided by the petitioner to establish that : (1) Polydextrose provides substantial improvement in the adhesion of the coating to tableted food supplements, and (2) it considerably improves the stability of colored coatings. The petitioner also established that the optimal level of polydextrose in the coating is 25 percent. With the coating constituting 5 percent of the tablet, the polydextrose content in the final coated product would be about 1.25 percent by weight or a maximum of 13 milligrams (mg) per tablet. Thus, even for heavy users of food supplements (consuming 5 to 10 tablets per day), the petitioner estimates that the maximum consumption of polydextrose from the proposed use of the additive in vitamin and mineral supplements would be no more than 130 mg per person per day (Ref. 1).

FDA concurs with the petitioner's estimates of consumer exposure to the additive from the petitioned use. Further, the agency finds that this consumption is insignificant compared to the cumulative intake of polydextrose from all currently regulated uses of the additive.

Accordingly, based on its evaluation of the data in the petition and other relevant material, FDA concludes that the proposed food additive use is safe, that the additive will achieve its intended technical effect, and that therefore, the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before July 7, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated July 31, 1996, from Z. S.Olempska-Beer, Division of Product Manufacture and Use, FDA, to R. M. Angeles concerning review of chemistry data in FAP 1A4258.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section § 172.841 is amended by revising paragraph (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(c) Polydextrose is used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use: Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products); chewing gum; confections and frostings; dressings for salads; frozen dairy desserts and mixes; fruit spreads; gelatins, puddings and fillings; hard and soft candy; peanut spread; sweet sauces, toppings, and syrups; film coatings on single and multiple vitamin and mineral supplement tablets.

* * * * *

Dated: May 8, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–14752 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 95N–0400]

Ophthalmic Devices: Reclassification of Rigid Gas Permeable Contact Lens Solution; Soft (Hydrophilic) Contact Lens Solution; and Contact Lens Heat Disinfecting Unit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule reclassifying from class III (premarket approval) to class II (special controls) rigid gas permeable contact lens solution, soft (hydrophilic) contact lens solution, and the contact lens heat disinfection unit. Collectively, these devices are referred to as transitional contact lens care products, which include saline solutions; in-eye lubricating/rewetting drops; disinfecting and conditioning products; contact lens cleaners; and heat disinfecting units. This reclassification is in accordance with provisions in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance describing the evidence that may demonstrate the substantial equivalence of new contact lens care products to legally marketed predicate lens care products.

EFFECTIVE DATE: July 7, 1997.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 321 *et. seq.*), as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, special controls; and class III, premarket approval.

The 1976 amendments broadened the definition of ''device'' in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class III all transitional devices (i.e., those devices previously regulated as new drugs). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 26–27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the **Federal Register** of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including rigid gas permeable contact lens solution (§ 886.5918 (21 CFR 886.5918)); soft (hydrophilic) contact lens solution (§ 886.5928 (21 CFR 886.5928)); and the contact lens heat disinfection unit (§ 886.5933 (21 CFR 886.5933)), to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 519 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the **Federal Register** of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act, provides that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, in the **Federal**