substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AWP HI D Barbers Point NAS, HI [Removed]

* * * * *

AWP HI D Kalaeloa Airport, Kapeloi, HI—[New]

Kalaeloa Airport, HI
(Lat 21°18′21″ N, long. 158°04′20″ W)

That airspace extending upward from the surface up to and including 2,500 feet MSL within a 4.3 mile radius of Kalaeloa Airport, excluding the airspace within the Honolulu, HI, Class B airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory, Pacific Chart Supplement.

* * * * *

Paragraph 6002 Class E airspace areas designated as a surface area for an airport

* * * * *

AWP HI E2 Barbers Point NAS, HI [Removed]

* * * * *

AWP HI E2 Kalaeloa Airport, Kapeloi, HI [New]

Kalaeloa Airport, HI
(Lat 21°18′21″ N, long. 158°04′20″ W)

That airspace extending upward from the surface within a 4.3 mile radius of Kalaeloa Airport, excluding the airspace within the Honolulu, HI, Class B airspace area. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6004 Class E airspace areas designated as an extension to a Class D surface area.

* * * * *

AWP HI E4 Barbers Point NAS, HI [Removed]

* * * * *

AWP HI E4 Kalaeloa Airport, Kapeloi, HI [New]

Kalaeloa Airport, HI
(Lat. 21°18′21″ N, long. 158°04′20″ W)
Point of Origin
(Lat. 21°18′21″ N, long. 158°03′54″ W)

That airspace extending upward from the surface within 3 miles each side of the 242° bearing from the Point of Origin, extending from the 4.3 mile radius of Kalaeloa Airport to 8.5 miles west of the Point of Origin and within 1.8 miles each side of the 289° bearing from the Point of Origin, extending from the 4.3 miles radius of the airport to 6.6 miles west of the Point of Origin, excluding the airspace within the Honolulu, HI, Class B airspace area.

Issued in Los Angeles, California, on July 27, 1999.

John Clancy,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 99–20524 Filed 8–11–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 99F–0001]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Sucralose

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 sucralose as a general purpose sweetener for food. This action is in response to a petition filed by McNeil Specialty Products Co.

DATES: This regulation is effective August 12, 1999; written objections and requests for a hearing by September 13, 1999.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3106.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** on January 11, 1999 (64 FR 1634), FDA announced that a food additive petition (FAP 8A4624) had been filed by McNeil Specialty Products, Co., 501 George St., New Brunswick, NJ 08903–2400. The petition proposed that the food additive regulations be amended at § 172.831 (21 CFR 172.831) to expand the permitted uses of sucralose to allow for use as a general purpose sweetener in food. FDA previously approved sucralose for use in 15 food categories under § 172.831 (64 FR 16417, April 3, 1998).

II. Identity

Sucralose is a disaccharide that is made from sucrose in a five-step process that selectively substitutes three atoms of chlorine for three hydroxyl groups in the sugar molecule. It is a free-flowing, white crystalline solid, product at an approximate purity of 98 percent, that is soluble in water and stable both in crystalline form and in most aqueous solutions. The sweetness intensity for sucralose in 320 to 1,000 times that of sucrose, depending on the food application.

Hydrolysis of sucralose may occur under conditions of prolonged storage at elevated temperatures in highly acidic aqueous food products. The hydrolysis products are the monosaccharides, 4-chloro-4-deoxy-galactose (4-CG) and 1,6-dichloro-1,6-dideoxyfructose (1,6-DCF).

III. Evaluation of Safety

In support of safety for the proposed expanded uses of sucralose, the petitioner referenced the toxicological safety data base submitted in food additive petition (FAP) 9A3987 that established the safety of the currently approved uses. Also referenced were the identity, manufacturing process, and specifications for the sweetener. In the new petition (FAP 8A4624), the petitioner submitted data concerning: (1) Use and typical use levels; (2) self-limiting levels; (3) proof of technical effect; (4) exposure; (5) stability; and (6) analysis in foods for both sucralose and its potential hydrolysis products.

In order to determine whether sucralose can be safety used as a general

purpose sweetener, the agency reevaluated the currently established acceptable daily intake (ADI) for sucralose, 5 milligrams per kilogram body weight per day (mg/kg bw/d) (Ref. 1) and determined that this ADI is still appropriate (Ref. 2). FDA also estimated new daily intakes (EDI) for the 90th percentile consumer of sucralose to include the expanded uses. The new EDI was derived from projections based on the amount of sucralose that may be used in the currently regulated food categories, the proposed food categories, and on data regarding the consumption levels of these particular foods. Based upon the data in the petition and other information, the agency established a no effect level (NOEL) for the hydrolysis products of sucralose at 30 mg/kg bw/d (Ref. 2).

To aid in the establishment of new exposure estimates for sucralose and its hydrolysis products, the petitioner submitted a Market Research Corporation of America (MRCA) report that addresses foods in which sucralose may be used and an updated report on the potential exposure for the hydrolysis products. From this information, the agency has determined that based on the expanded uses, the cumulative exposure to sucralose could increase to 2.4 mg/kg bw/d and the cumulative exposure to its hydrolysis products to 0.007 mg/kg bw/d (Ref. 3). The agency concludes: Exposure to sucralose will remain below the previously established ADI of 5.0 mg/kg bw/d for sucralose, and exposure to the hydrolysis products will remain far below the no effect level of 30 mg/kg bw/d (Refs. 2 and 3).

IV. Conclusions

From the review of all the information available on sucralose and its hydrolysis products, the agency concludes that sucralose may be safely used as a sweetener in food generally (Refs. 2 and 3).

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.

V. Environmental

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.

VI. Paperwork Reduction Act 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 13, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularly 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 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.

VIII. References

The following references have 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. Addendum memorandum from Whiteside, Scientific Support Branch, FDA, to Anderson, Novel Ingredients Branch, FDA, November 13, 1997.

2. Memorandum from Whiteside, Division of Health Effects Evaluation, FDA, to Anderson, Regulatory Policy Branch, February 25, 1999.

3. Memorandum from DiNovi, Division Product Manufacture and Use, FDA, to Anderson, Division of Product Policy, FDA, October 22, 1998.

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, 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: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.831 is amended by removing the introductory paragraph and by revising paragraph (c) to read as follows:

§ 172.831 Sucralose.

* * * * *

(c)The additive may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

* * * * *

Dated: August 5, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–20888 Filed 8–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Sulfadimethoxine, Ormetoprim

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Roche Vitamins, Inc. The supplemental NADA provides for a change in the name of a duck pathogen. Infections of the pathogen are controlled by use of