

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 172

[Docket No. 95F-0305]

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 bulking agent, texturizer, or both in fruit and water ices. This action is in response to a petition filed by Pfizer, Inc.

DATES: This rule is effective [insert date of publication in the Federal Register]. Submit written objections and requests for a hearing by [insert date 30 days after date of publication in the Federal Register].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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:

I. Introduction

In a notice published in the Federal Register of September 20, 1995 (60 FR 48716), FDA announced that a food additive petition (FAP 5A4478) had been filed by Pfizer, Inc., 235 East

42d St., New York, NY 10017–5755. Pfizer, Inc., subsequently announced the sale of the Pfizer Food Science Group and the transfer of the petition to Cultor Food Science, Inc., 430 Saw Mill River Rd., Ardsley, NY 10502. Recently, the petitioner announced a name change from Cultor Food Science, Inc., to Danisco Cultor America, Inc. (Danisco), to reflect the acquisition of the company by Danisco. The petition proposed to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to provide for the safe use of polydextrose as a bulking agent, texturizer, or both in fruit and water ices. Polydextrose is intended to replace all, or in part, fully-caloric ingredients to produce reduced- or lower-calorie and/or reduced- or lower-sugar fruit and water ices. The intent of this petitioned use is to enable manufacturers to formulate all types of frozen desserts, whether or not they contain dairy ingredients.

The proposed use level of polydextrose in fruit and water ices is 5 to 15 percent with the weighted mean use level estimated to be 10 percent. The petitioner claims that this use level makes possible the formulation of lower-calorie fruit and water ices that compare favorably with prototypes that contain no polydextrose. The petitioner claims that the 15 percent use level is technologically self-limiting because of less than optimum mouthfeel, increased iciness, unfavorable taste and reduced acceptability at higher levels. The petitioner submitted data from sensory studies to substantiate this claim.

## **II. Conclusions**

FDA estimated that the mean chronic consumption of polydextrose from the proposed use in fruit and water ices is 0.1 gram per person per day (g/p/d). The agency considers this consumption insignificant compared to the estimated cumulative intake of polydextrose of 18 g/p/d from all currently regulated uses of the additive. Therefore, FDA concludes that there will be a negligible increase in dietary exposure to polydextrose from the issuance of this amendment to the regulation (Ref. 1).

FDA has evaluated data in the petition and other relevant material in its files. Based on this information, the agency concludes that: (1) The proposed food additive use is safe, (2) the additive

will achieve its intended technical effect, and therefore, (3) the regulation in § 172.841 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.

An inadvertent error was made in the **Federal Register** of October 30, 2000 (65 FR 64604 at 64605) when “dressings for salads” was inadvertently combined with “confections and frostings” in § 172.841(c)(3). This document corrects that error in § 172.841 by designating “dressings for salads” as paragraph (c)(4) and redesignating paragraphs (c)(4) through (c)(11) as paragraphs (c)(5) through (c)(12).

### **III. Environmental Impact**

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner’s environmental assessment. The agency received no comments in response to that notice.

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.

#### **IV. Paperwork Reduction Act of 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.

#### **V. Objections**

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. 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 are to be submitted and are to 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.

#### **VI. References**

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 from Z. Olempska-Beer, Division of Product Manufacture and Use, FDA, to R. Angeles, Division of Product Policy, FDA, November 21, 1995.

## 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:** 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.**

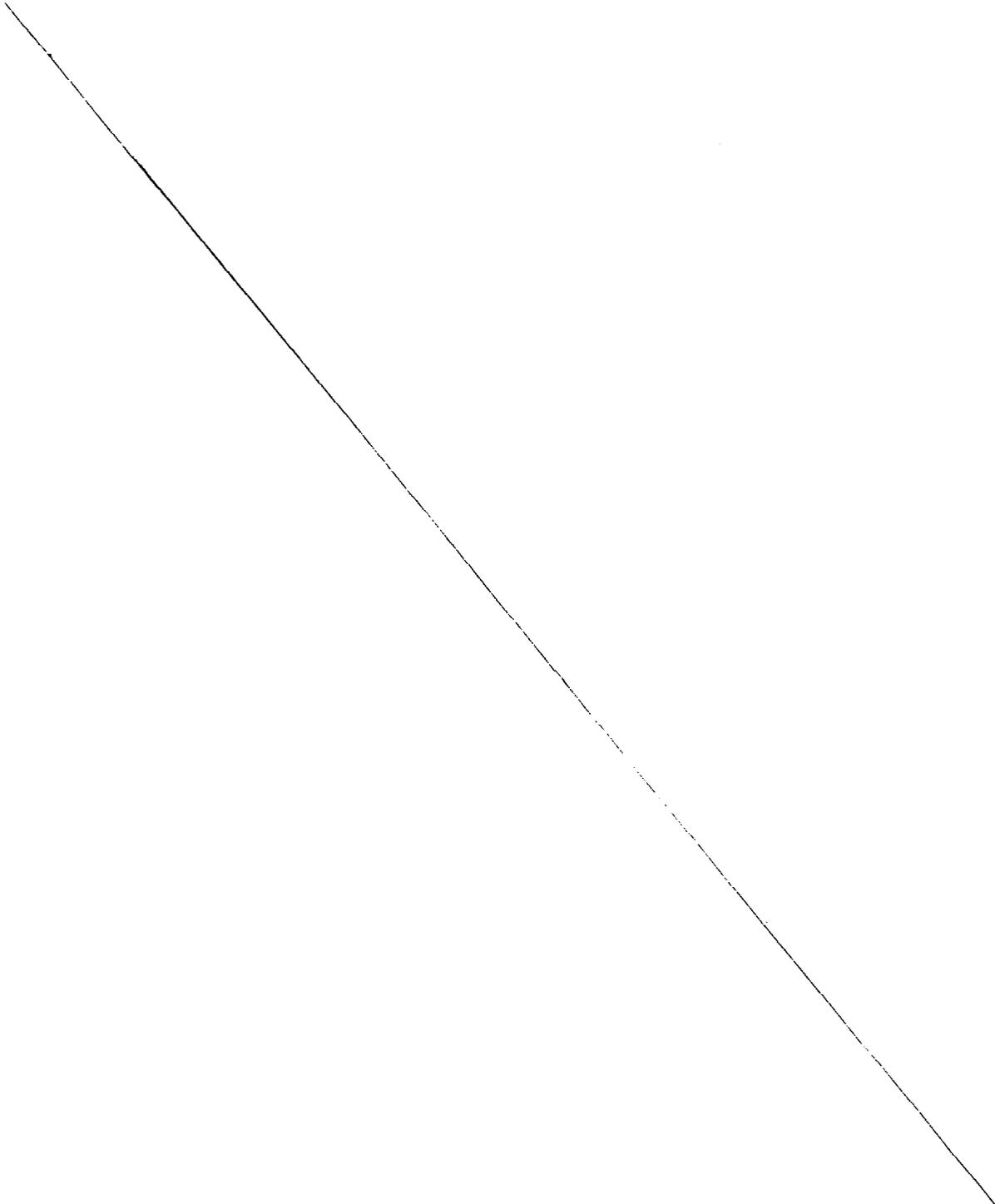
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(c) Polydextrose is used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use:

- (1) Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies, cakes, cookies, and similar baked products);
- (2) Chewing gum;
- (3) Confections and frostings;
- (4) Dressings for salads;
- (5) Film coatings on single and multiple vitamin and mineral supplement tablets;
- (6) Frozen dairy desserts and mixes;
- (7) Fruit and water ices;
- (8) Fruit spreads;
- (9) Gelatins, puddings and fillings;

(10) Hard and soft candy;

(11) Peanut spread;



(12) Sweet sauces, toppings, and syrups;

(13) Tablespreads.

\* \* \* \* \*

Dated: 12-12-00  
December 12, 2000

*Janice F. Oliver*

Janice F. Oliver  
Deputy Director  
Center for Food Safety and Nutrition

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

*J. Windsor*

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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