

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 172

[Docket No. 97 F-0388]

**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 permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996. This action is in response to a petition filed by Cultor Food Science, Inc.

DATES: This regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*). The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51 of certain publications in § 172.841(b) (21 CFR 172.841(b), (*insert 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: In a notice published in the Federal Register of September 25, 1997 (62 FR 50387), FDA announced that a food additive petition (FAP 7A4556) had been filed by **Cultor Food Science, Inc.**, 205 East 42d St., New York, NY 10017, proposing that §172.841 *Polydextrose* (21 CFR 172.841) be amended to permit aqueous transition metal catalytic hydrogenation in the production of **polydextrose** and to adopt the specifications for **polydextrose** of the Food Chemicals **Codex**, 4th ed., 1996, pp. 297–300.

The proposed optional transition metal catalytic hydrogenation step in the production of **polydextrose** yields a partially reduced form of **polydextrose** in which the glucose moiety of glucose-terminated **polydextrose** polymers and the residual glucose monomers are converted to **sorbitol** moieties. The petitioner submitted data demonstrating that this partially reduced form of **polydextrose** is functionally equivalent to the currently regulated **polydextrose** and that no new chemical species are formed as a result of the proposed hydrogenation step. These data also show that the components of **polydextrose** produced by the proposed hydrogenation step are the same as the compounds of the currently regulated **polydextrose** and that only the relative amounts of **sorbitol-terminated polydextrose** and of free **sorbitol** are changed. The proposed adoption of the specifications for **polydextrose** in the Food Chemicals **Codex**, 4th ed., will allow the partially reduced form of **polydextrose**, with increased residual free **sorbitol**, to meet the specifications for **polydextrose**.

No new uses and no changes in current use levels of **polydextrose** are proposed in the petition. **Polydextrose** produced by the proposed hydrogenation step is expected to be used as a replacement for the currently regulated **polydextrose**. Therefore, FDA concludes that there will be no increase in dietary exposure to **polydextrose** from the promulgation of this amendment to the regulation (Ref. 1).

Based on its evaluation of the data in the petition and other relevant material in its files, FDA concludes that the reduced form of **polydextrose** produced by the proposed optional

hydrogenation step is safe, that it 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.

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

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the **Federal Register**)*, 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 September 27, 1997, from M. DiNovi, Division of Product Manufacture and Use, FDA, to R. M. Angeles, Division of Product Policy, FDA.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate 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 paragraphs (a)(2) and (b) to read as follows:

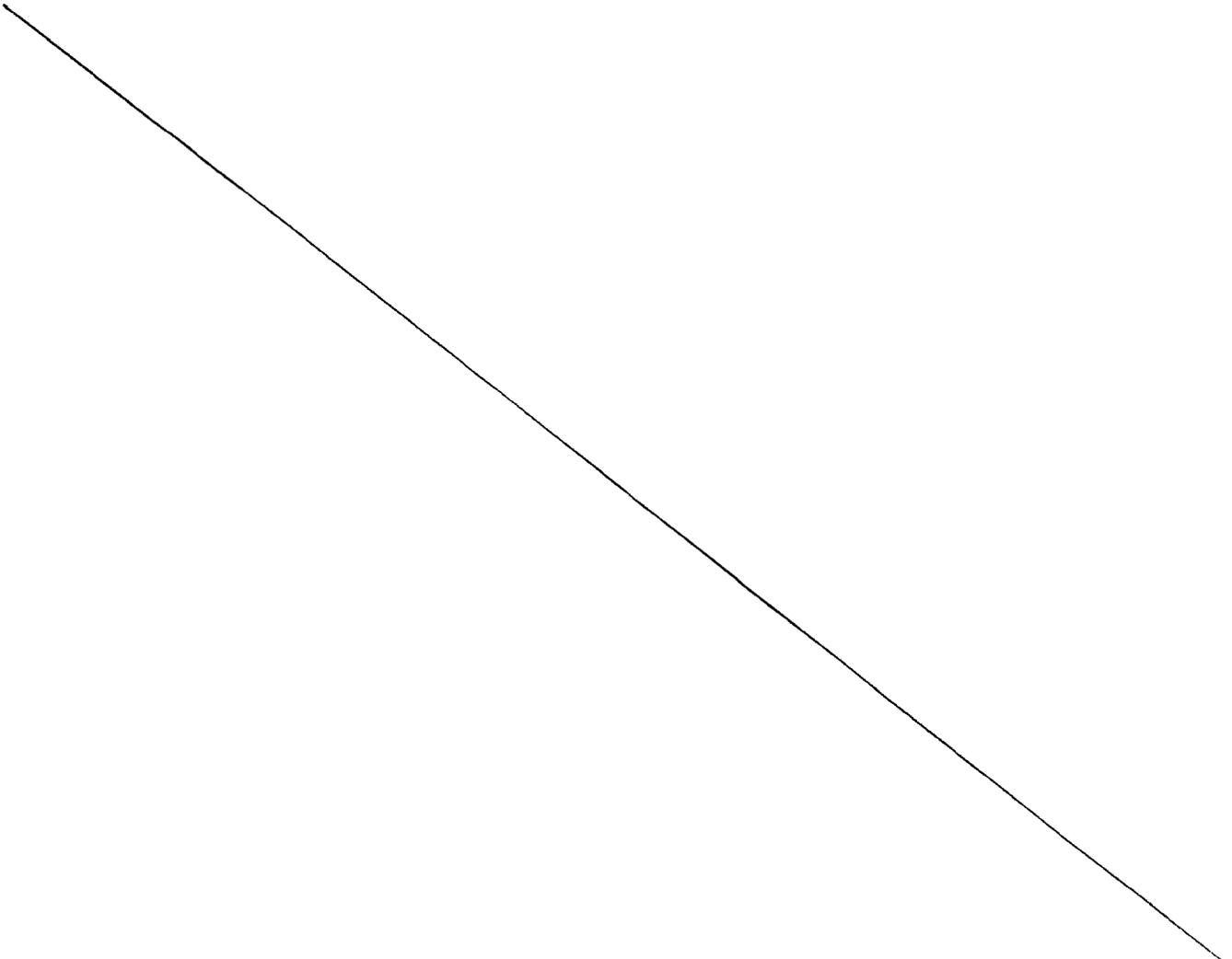
§ 172.841 Polydextrose.

* * * * *

(a) * * *

(2) Polydextrose maybe partially neutralized with potassium hydroxide, or partially reduced by transition metal catalytic hydrogenation in aqueous solution.

(b) The additive meets the specifications of the “Food Chemicals Codex, ” 4th ed. (1996), pp. 297–300, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition’s



Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC,

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Dated: 10/16/98
October 16, 1998

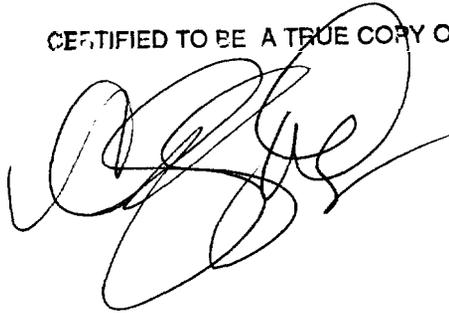
L. Robert Lake

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be the initials 'RL' with a large flourish.