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Dated: October 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 97F-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 October 28, 1998; written objections and requests for a hearing by November 27, 1998. 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), October 28, 1998.

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 November 27, 1998, 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 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 paragraphs (a)(2) and (b) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(a) * * *

(2) Polydextrose may be 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: October 18, 1998.

L. Robert Lake,

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

[FR Doc. 98–28780 Filed 10–27–98; 8:45 am]

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POSTAL SERVICE

39 CFR Part 111

[Docket No. R97–1]

**Amendments to the Rate, Fee, and
Classification Changes and the
Domestic Mail Manual Implementation
Standards**

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This final rule sets forth revised rates, fees, and mail preparation standards for In-County Periodicals

automation mail, Destination Delivery Unit Parcel Post, and Library Mail adopted by the Postal Service in the October 5, 1998, Decision of the Governors of the Postal Service in Postal Rate Commission Docket No. R97–1. It also contains corrections and additions to the implementation standards in the final rule published in the **Federal Register** on Tuesday, July 14, 1998 (63 FR 37946).

EFFECTIVE DATE: This final rule is effective at 12:01 a.m. on January 10, 1999.

FOR FURTHER INFORMATION CONTACT: Lynn M. Martin, 202–268–6351.

SUPPLEMENTARY INFORMATION: In their Decision on June 29, 1998, in Docket No. R97–1, the Governors of the Postal Service returned three matters to the Postal Rate Commission for reconsideration. On September 24, 1998, the Commission issued its further Recommended Decision on those matters. The Governors approved the rate and classification changes included within the further Recommended Decision on October 5, 1998, and the Board set the implementation date for these changes as January 10, 1999, to coincide with the other changes from Docket No. R97–1 being implemented on that date. The categories affected by these changes are In-County Periodicals automation mail, Destination Delivery Unit Parcel Post, and Library Mail.

This rule contains the Domestic Mail Manual changes adopted by the Postal Service to implement the Governors' October 5, 1998, decision. This rule also contains clarifications, corrections, and additions to the final rule published in the **Federal Register** on July 14, 1998 (63 FR 37946) that contained Domestic Mail Manual changes adopted by the Postal Service to implement the June 29, 1998, Decision of the Governors of the Postal Service in Postal Rate Commission Docket No. R97–1. Part A of this rule contains revisions to portions of the July 14, 1998, **Federal Register** that did not contain Domestic Mail Manual language. Part B describes the changes to the Domestic Mail Manual. Part C contains the revisions to the Domestic Mail Manual. The DMM amendments and revisions published in this rule reflect renumbering of the DMM based on revisions published subsequent to the July 14 final rule. The revised DMM standards will take effect on January 10, 1999.

A. Corrections to the Federal Register

In the **Federal Register** issue of July 14, 1998 (63 FR 37946) on page 37950, third column, under 5a, delete the third sentence and replace it with the

following: "Nonprofit ECR pound rates will decrease. Nonprofit subclass pound rates will increase."

In the **Federal Register** issue of July 14, 1998 (63 FR 37946) on page 38033, third column, delete the last sentence and replace it with the following: "An appropriate amendment to 39 CFR 111.3 will be published to reflect these changes."

B. Domestic Mail Manual Amendments and Revisions

1. C010.1.3 is amended to reflect the new oversized Parcel Post dimensions.

2. C050.5.0 is amended to clarify that merchandise samples prepared with detached address labels are considered irregular parcels only if they are not letter-size and are not flat-size. This means that merchandise samples that are letter-size or flat-size as defined in C050 will not be subject to the residual shape surcharge.

3. D100.2.1 is amended to change the phrase "single-piece rate Priority Mail" to "Priority Mail."

4. D100.2.6 is amended to change the phrase "single-piece rate Priority Mail" to "Priority Mail."

5. E630.2.5 concerning eligibility of Bound Printed Matter for the barcoded discount is revised to remove references to 5-digit bundles when preparing Presorted Bound Printed Matter under the sortation requirements for machinable parcels. This section is further corrected to refer to 5-digit bundles under the provisions for preparing bedloaded bundles, and to clarify that such 5-digit bundles may qualify for the barcoded discount. Other sortation levels of bedloaded bundles will not qualify for the barcoded discount.

6. The requirements for eligibility of Special Standard Mail for barcoded discounts are moved from E630.4.7 to E630.3.1.

7. E630.5.1 is revised to add requirements for eligibility of Library Mail for Presorted 5-digit rates and Presorted BMC rates. The requirements for eligibility of Library Mail for barcoded discounts are moved from E630.5.8 to E630.5.1. E630.5.3, which specified that mailings of 1,000 or more identical weight pieces of single-piece rate Library Mail must be presorted, is deleted. Single-piece rate Library Mail mailings of 1,000 or more identical-weight pieces will no longer be required to be presorted. E630.5.4 through E630.5.7 is renumbered as E630.5.3 through E630.5.6.

8. Former E630.6.0, Bulk Parcel Post, is renumbered as E630.7.0.