Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1580, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m., or by calling Thomson Financial at (800) 638–8241. Electronic copies are available on the Commission's Web site. The address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml.* You can also photocopy the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Dated: August 15, 2007.

By the Commission.

Florence E. Harmon,

Deputy Secretary .

[FR Doc. E7–16414 Filed 8–20–07; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2006F–0059]

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, formulation aid, humectant, and texturizer in all foods, except meat and poultry, baby foods, and infant formula. This action is in response to a petition filed by Danisco USA, Inc.

DATES: This rule is effective August 21, 2007. Submit written or electronic objections and requests for a hearing by September 20, 2007. See section VII of the **SUPPLEMENTARY INFORMATION** section of this document for information on the filing of objections. 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)) as of August 21, 2007.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2006F–0059, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of February 15, 2006 (71 FR 7975), amended April 27, 2006 (71 FR 24856), FDA announced that a food additive petition (FAP 6A4763) had been filed by Danisco USA, Inc., 440 Saw Mill River Rd., Ardsley, NY 10502–2605. The petition proposed to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841). Currently, § 172.841 lists 13 specific categories of foods in which polydextrose may be used safely as a bulking agent, formulation aid, humectant, and texturizer. The petition proposed to amend § 172.841 to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry.

The petition also proposed to incorporate by reference the specifications for polydextrose in the 5th edition of the Food Chemicals Codex (FCC V), effective January 1, 2004. After the petition was filed, Danisco amended the petition to exclude the proposed uses of polydextrose in baby food and infant formula.

II. Determination of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, existing toxicological data, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

The petitioner estimates that the cumulative intake of polydextrose from all currently-regulated and proposed uses of the additive will result in an exposure to the additive of 16 grams per person per day (g/p/d) (mean) and 31 g/p/d (90th percentile) for all ages (Ref. 1). The previous FDA intake estimate for polydextrose from currently-regulated uses was 18 g/p/d and 30 g/p/d at the mean and 90th percentile, respectively, for persons aged 2 years and above. Despite the additional proposed uses, the petitioner's intake estimate for polydextrose did not differ significantly from the previous FDA intake estimate because it is based on revised use levels and current uses of polydextrose that are more representative of actual uses of polydextrose in food than those used in FDA's previous intake estimate. FDA agrees with the petitioner's intake estimate for polydextrose and concludes that it is sufficiently conservative (Ref. 1). Because consumer exposure to polydextrose has not changed significantly as a result of the petitioned uses, no new toxicological testing is necessary to ensure that the additional uses proposed in the petition, as amended, will be safe. Therefore, FDA concludes that there is a reasonable certainty that no harm from exposure to polydextrose would result from the additional petitioned uses.

The agency also considered the potential for laxation effect due to excessive consumption of polydextrose in sensitive individuals. Currently, the regulation setting out approved food additive uses for polydextrose requires that consumers be informed of this potential effect through special labeling of products containing more than 15 g of polydextrose per serving (21 CFR 172.841(e)). The agency has considered the cumulative effect of the additional petitioned uses and has concluded that because there will be effectively no increase in dietary exposure to polydextrose the current labeling requirement is adequate to protect the public. Accordingly, the agency is amending § 172.841 of the food additive regulations to provide for the use of polydextrose in all foods, except meat, poultry, baby food, and infant formula.

III. Specifications for Polydextrose

As stated previously, the petition proposes that § 172.841 be amended by adopting the specifications for polydextrose in FCC V. Currently, § 172.841 incorporates by reference the specifications of the 4th edition of the Food Chemicals Codex (FCC IV), 1996. The differences between the specifications in the monograph for polydextrose in FCC IV and FCC V are discussed in the amended filing notice published in the **Federal Register** of April 27, 2006. FDA received no comments on the proposed adoption of the FCC V specifications for polydextrose. Subsequent to the publication of the amended filing notice, FDA learned that FCC published an erratum to the polydextrose monograph in the First Supplement to the 5th Edition of the Food Chemicals Codex (effective March 1, 2006). The erratum contained additional instructions on preparing a standard curve for the assay, but did not include any changes to the specifications.

FDA has reviewed the specifications in FCC V and agrees that § 172.841 should be amended by adopting the specifications in FCC V.

IV. Conclusion

FDA reviewed data and information in the petition and other relevant material to evaluate the safety of the proposed use of polydextrose in all foods, except meat and poultry, baby food, and infant formula. Based on its evaluation, FDA concludes that the uses proposed in the petition are safe, and therefore, § 172.841 should be amended as set forth in this document. 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 will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). 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 Impact

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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1995

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.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

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

1. Memorandum from Folmer, Chemistry Review Team, Division of Petition Review, to DeLeo, Regulatory Group I, Division of Petition Review, June 20, 2006.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, 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 paragraphs (b) and (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(b) The additive meets the specifications of the ''Food Chemicals Codex,'' 5th ed. (January 1, 2004), pp. 336–339, and the First Supplement to the 5th Edition of the Food Chemicals Codex (March 1, 2006), p. 37, which are incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from The National Academies Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address *http://www.nap.edu*). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) When standards of identity established under section 401 of the act do not preclude such use, polydextrose may be used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry, baby food, and infant formula.

* * * * *

Dated: August 14, 2007.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. E7–16322 Filed 8–20–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2006–0526; FRL–8446–1]

Approval and Promulgation of Implementation Plans; Arizona—Phoenix PM–10 Nonattainment Area; Salt River Area Plan for Attainment of the 24-hour PM–10 Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval under the Clean Air Act (CAA) of provisions of the Revised PM–10 State Implementation Plan (SIP) for the Salt River Area submitted by the State of Arizona to EPA in October and November 2005. These submittals include adopted rules, resolutions and measures that address particulate matter (PM–10) emissions from fugitive dust sources.

DATES: *Effective Date:* This rule is effective on September 20, 2007.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2006–0526 for this action. The index to the docket is available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., Confidential Business Information). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Mae Wang, EPA Region IX, (415) 947–4124, *wang.mae@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. Proposed Action

On July 12, 2006 (71 FR 39251), EPA proposed to approve the rules, resolutions and measures listed below into the Arizona PM–10 SIP pursuant to the cited CAA sections. We also proposed on July 12, 2006, to approve Maricopa County Air Quality Department (MCAQD) Rule 316, ''Nonmetallic Mineral Processing,'' adopted on June 8, 2005. In this final rule we are approving all the items listed below. EPA is not, however, including Rule 316 in this final action because we are re-evaluating the rule and expect to address it in a separate rulemaking.

TABLE I

Rule/measure/commitment	Relevant CAA section(s)
Maricopa County Air Quality Department (MCAQD) Rule 325, ''Brick and Structural Clay Products (BSCP) Manufacturing,'' adopted August 10, 2005.	189(b)(1)(B) and 188(e).
MCAQD Rule 310, ''Fugitive Dust,'' adopted April 7, 2004	189(b) and 188(e) for subsections 304.5 and 502. 110(a) for other subsections.
MCAQD Rule 310.01, ''Fugitive Dust From Open Areas, Vacant Lots, Unpaved Parking Lots, and Unpaved Roadways,'' adopted February 17, 2005.	110(a).
MCAQD Appendix C, ''Fugitive Dust Test Methods,'' adopted April 7, 2004	189(b) and 188(e) for subsection 3.3.2. 110(a) for other subsections.
MCAQD Appendix F, ''Soil Designations,'' adopted April 7, 2004	189(b) and 188(e).
MCAQD ''Application for Dust Control Permit,'' adopted June 22, 2005[1]	189(b) and 188(e) for Section 2, subsections 10 and 11, and Section 3, subsection I. 110(a) for other subsections.
MCAQD 'Guidance for Application for Dust Control Permit,'' adopted June 22, 2005[2]	189(b) and 188(e) for Section 2, subsection 13, and Section 3. 110(a) for other subsections.
Maricopa County Board Resolution No. C–85–05–005–0–00, adopted January 19, 2005	189(b) for enforcement resource provisions of Measures 1 through 4. 110(a) for other provisions, including Measure 5.
City of Phoenix Resolution No. 20114, adopted June 16, 2004	110(a).
Resolutions from 17 municipalities[3] and the Arizona Department of Transportation, adopted on various dates.	110(a).

[1] The reference to an adoption date of July 1, 2005, in the proposed rule was a clerical error (71 FR at 39253).
[2] See footnote 1.
[3] The reference to resolutions from 18 municipalities in the proposed rule was a clerical error (71 FR at 39253).