

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006F-0059]

Danisco USA, Inc.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Danisco USA, Inc., to indicate that the petition proposes to amend the food additive regulations at 21 CFR 172.841 by incorporating by reference the specifications for polydextrose in the 5th edition of the Food Chemicals Codex (FCC), 2003.

ADDRESSES: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1302.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of February 15, 2006 (71 FR 7975), 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) to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry. After publication of the filing notice, FDA learned that the petition also proposed to update § 172.841 by incorporating by reference the specifications for polydextrose in the FCC, 5th ed., 2003. Currently, § 172.841 incorporates by reference the specifications of FCC, 4th ed., 1996.

The agency compared specifications in the monograph for polydextrose in the 4th and 5th editions of the FCC and found that the 5th edition retains the lead limit of 0.5 milligram(mg)/kilogram(kg), but no longer lists a specification limit of 5 mg/kg for heavy metals as lead. The 5th edition of the FCC eliminated the heavy metals as lead test from most monographs in favor of including individual specifications for relevant heavy metals. In addition, the 5th edition added a nickel specification of 2 mg/kg for hydrogenated polydextrose, as well as modified the pH specification of a 10 percent solution of untreated polydextrose from "not less than 2.5" (4th edition) to "between 2.5 and 7.0" (5th edition). The name of the specification for 5-Hydroxymethylfurfural has also changed from "5-Hydroxymethylfurfural" (4th edition) to "5-Hydroxymethylfurfural and Related Compounds" (5th edition), although the test and

equation used to determine the level have remained the same. The agency has placed copies of the polydextrose

monograph in the 4th and 5th editions of the FCC on public display at the Division of Dockets Management (see ADDRESSES) for public review.

Dated: March 20, 2006.

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