

# WORLD TRADE ORGANIZATION

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22 November 2004

(04-5067)

Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

### Addendum

The following communication, dated 17 November 2004, is being circulated at the request of the Delegation of the United States.

#### Final Rule; Food Additives Permitted in Food on an Interim Basis or in Contact With Food Pending Additional Study; Mannitol

The Food and Drug Administration published a Final Rule in the Federal Register on 15 November 2004 (69 FR 65540) amending the food additive regulations to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, or maltose by the action of the microorganism *Lactobacillus intermedius (fermentum)*. This action is in response to a petition filed by zuChem, Inc. This document can be obtained online at:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-25243.htm>

or

<http://frwebgate2.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=53806318174+1+0+0&WASAction=retrieve>

This rule is effective 15 November 2004. Any person who will be adversely affected by this regulation may file written or electronic objections and requests for a hearing with the Division of Dockets Management by 15 December 2004. Submit written objections and requests for a hearing identified by Docket No. 2004F-0066, by any of the following methods:

- 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.
- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include Docket No. 2004F-0066 in the subject line of your e-mail message.
- 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.

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.

In a notice published in the Federal Register of 19 February 2004 (69 FR 7759), the Food and Drug Administration announced that a food additive petition (FAP 4A4754) had been filed. The

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petition proposed to amend the food additive regulations in Sec. 180.25 Mannitol (21 CFR 180.25) to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, and maltose by the action of the microorganism *L. intermedius* (fermentum).

For further information contact: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1282.

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