

document are, therefore, \$83,000. Respondents are already required to disclose the quantitative amount and the percentage of the daily value of a dietary ingredient on a per serving basis as part of the nutrition information for dietary supplements. Respondents may also provide such information on a per unit basis. The information provided for under the proposed rule would be generated by simple extrapolation from that information.

Dated: November 2, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-28105 Filed 11-8-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01F-0484]

Anitox Corp.; Filing of Food Additive Petition (Animal Use); Formaldehyde

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Anitox Corp. has filed a petition proposing that the food additive regulations be amended to allow a variable usage rate of 2.0 to 5.4 pounds (lb) of formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution) per ton of animal feeds for feed ingredients.

DATES: Submit written or electronic comments on the petitioner's environmental assessment by January 23, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Henry E. Ekperigin, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0174.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2245) has been filed by Anitox Corp., 1055 Progress Circle, P.O. Box 490310, Lawrenceville, GA 30043. The petition proposes to amend the food additive regulations in part 573—Food

Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to allow a variable usage rate of 2.0 to 5.4 lb of formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution) per ton of animal feeds for feed ingredients.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental information submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment.

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments by January 23, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: October 31, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-28103 Filed 11-8-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1277]

Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance

document entitled "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds." The purpose of this guidance is to identify for the industry fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. The agency is also announcing the availability of the final supporting documents entitled "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and "Background Paper in Support of Fumonisin Levels in Animal Feed."

DATES: Submit written or electronic comments concerning the final guidance and the final supporting documents at any time.

ADDRESSES: Submit written comments on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the final guidance entitled "Guidance for Industry: Fumonisin Level in Human Foods and Animal Feeds" to Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN) (address below), or Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855, 301-594-1755. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT:

Henry Kim, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-0631, or Randall Lovell, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0176.

SUPPLEMENTARY INFORMATION:

I. Background

On June 6, 2000, FDA issued a draft guidance document that presented recommended levels of fumonisins in corn used for production of human