Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Inpatient Rehabilitation Facilities—Patient Assessment Instrument.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–28219 Filed 11–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0335]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 10, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day''' Basis

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(F)) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for dietary supplements in nutrition labeling in 21 CFR 101.36 in the September 23, 1997, final rule (62 FR 49826). FDA published a proposed rule in the **Federal Register** of January 12, 1999 (64 FR 1765), to amend its nutrition labeling regulations for dietary supplements. This amendment would provide that the quantitative amount and the percentage of the daily value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis. The proposed rule stated that this voluntary information may be provided if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

In the **Federal Register** of August 14, 2001 (66 FR 42663), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
101.36(d)	85	10	850	0.25	$83,000	213

[1] There are no capital costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA's knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there was a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85 of the dietary supplement suppliers, would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10 of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products. FDA estimates that at least 90 percent of firms would coordinate the addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately $50 per label for 760 labels, or $38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately $500 per label (64 FR 1765 at 1769) for 90 labels, or $45,000 total. The estimated total operating costs in table 1 of this

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]

BILLING CODE 4160–01–S

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