

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 2003N-0397]
Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for exemption from the food additive listing regulation requirements that are submitted under part 170 (21 CFR part 170).

DATES: Submit written or electronic comments on the collection of information by November 17, 2003.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget

(OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39 (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the act, (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the act, there is either a regulation authorizing

its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

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 Hours
170.39	6	1	6	48	288

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting estimate is based on information received from representatives of the food packaging and processing industries and agency records. In the past, FDA has typically received 60 threshold of regulation exemption requests per year. However, it is estimated that up to 90 percent of the requests that would have been previously submitted under § 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910-0495). The main advantages of the premarket notification process is that notifiers are guaranteed a decision by FDA within 120 days of receipt of an acceptable notification and, once approved, an effective notification is exclusive to the manufacturer or supplier who submitted the request. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is identical to that required under § 170.39, the burden on industry for premarket notifications will be similar to the burden for requests submitted under the existing threshold of regulation process.

As indicated previously in this document, it is estimated that approximately six requests per year will be submitted under the threshold of regulation exemption process of § 170.39. The threshold of regulation process offers one advantage over the premarket notification process in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at <http://www.cfsan.fda.gov>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive

petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: September 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0186]

Guidance for Industry on Use of Material From Deer and Elk in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance (#158) entitled "Use of Material From Deer and Elk in Animal Feed." This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from deer and elk that are positive for chronic wasting disease (CWD) or are considered at high risk for CWD.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20855. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of this guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl.,

Rockville, MD 20855, 301-827-0177, e-mail: bpritchett@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 16, 2003 (68 FR 26628), FDA published a notice of availability for a draft guidance entitled "Use of Material from Deer and Elk in Animal Feed" giving interested persons until June 16, 2003, to submit comments. FDA considered all comments received.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This level 1 guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the final guidance at any time. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the final guidance document entitled "Use of Material From Deer and Elk in Animal Feed" from the Center for Veterinary Medicine home page at <http://www.fda.gov/cvm>.