

petitions for § 10.85 (advisory opinions), the agency received approximately 2 requests annually, each required an average of 16 hours of preparation time.

Dated: November 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0290]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**DATES:** Fax written comments on the collection of information by December 16, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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

**Importer's Entry Notice—(OMB Control Number 0910-0046)—Extension**

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of goods to their final destinations; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time that person files an entry for import with the U.S. Custom Service. FDA uses this information to make admissibility decisions about FDA-regulated products

offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2004 was 6,626,827. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA while contacting potential respondents. Disclaimer entries are not FDA commodities.

In the **Federal Register** of August 3, 2005 (70 FR 44656), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received.

The Government of Canada is concerned that the methodology used does not take into consideration the additional burden of FDA's interim final prior notice and regulation rules which came into effect December 2003. They urged FDA to amend the methodology used to take into consideration the additional burden associated with all requirements for providing information concerning foreign-origin FDA-regulated foods. Of particular concern is the burden resulting from the implementation of the prior notice and regulation rules under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The burden for the prior notice and regulation rules is reported and approved under OMB Control Number 0910-0520; expiration date October 31, 2006.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 U.S.C. Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801	3,406	1,089	3,709,134	.14	519,279

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

Dated: November 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0427]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

**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 requirements for filing objections and requests for a hearing on a regulation or order.

**DATES:** Submit written or electronic comments on the collection of information by January 17, 2006.

**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:

Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

#### Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910-0184)—Extension

Under part 12 (21 CFR part 12), § 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), sets forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	10	1	10	20	200

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