

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 100 | 1 | 100 | 15 | 1,500 |

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

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible for the AP program. Also 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates that there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion in the AP program. Based on informal communications with industry, FDA estimates that approximately 100 of these manufacturers may apply to use an AP in any given year.

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0209]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substances Notification System

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 the collection of information associated with the Food Contact Substances Notification System.

DATES: Submit written or electronic comments on the collection of information by August 8, 2005.

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.

Food Contact Substances Notification System—21 CFR 170.101 and 170.106—(OMB Control Number 0910-0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the act defines a "food contact substance" as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of food contact substances except where FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the act is necessary to provide adequate assurance of safety or where FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) require that a food contact notification (FCN) include FDA Form 3480 entitled "Notification for New Use of a Food Contact Substance" and that a notification for a food contact substance formulation include FDA Form 3479 entitled "Notification for a Food Contact Substance Formulation." These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents:
Manufacturers of food contact substances.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Form | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-------------------------------------|--------------------|----------|-------------------------------|------------------------|--------------------|-------------|
| 170.106 ² (Category A) | 5 | FDA 3479 | 1 | 5 | 2 | 10 |
| 170.101 ^{3,7} (Category B) | 5 | FDA 3480 | 1 | 5 | 25 | 125 |
| 170.101 ^{4,7} (Category C) | 5 | FDA 3480 | 2 | 10 | 120 | 1,200 |
| 170.101 ^{5,7} (Category D) | 33 | FDA 3480 | 2 | 66 | 150 | 9,900 |
| 170.101 ^{6,7} (Category E) | 30 | FDA 3480 | 1 | 30 | 150 | 4,500 |
| Total | | | | | | 15,735 |

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

² Notifications for food contact substance formulations and food contact articles. These notifications require the submission of FDA Form 3479 ("Notification for a Food Contact Substance Formulation") only.

³ Duplicate notifications for uses of food contact substances.

⁴ Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.

⁵ Notifications for uses that are the subject of moderately complex food additive petitions.

⁶ Notifications for uses that are the subject of very complex food additive petitions.

⁷ These notifications require the submission of FDA Form 3480.

These estimates are based on FDA's experience with the food contact substances notification system.

- Based on input from industry sources, FDA estimates that the agency will receive approximately five notifications annually for food contact substance formulations.

- FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out FDA Form 3480, verifying that a previous notification is effective, and preparing necessary documentation.

- Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (the third, fourth and fifth rows of table 1 of this document).

- FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0003]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

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 July 7, 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 written 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: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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. This notice solicits comments on regulations requiring the distribution of patient labeling, called Medication Guides, for certain products that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information.

Prescription Drug Product Labeling; Medication Guide Requirements—(OMB Control Number 0910-0393—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use