Description of Respondents: Manufacturers of food contact substances.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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.

[FR Doc. 05–11265 Filed 6–6–05; 8:45 am]

BILLING CODE 4160–01–S

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

certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA, and the estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

21 CFR 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

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
208.20	8	1	8	320	2,560
314.70(b)(3)(ii) and 601.12(f)	2	1	2	72	144
208.24(e)	55,000	20	1,100,000	.0014	1,540
208.26(a)	1	1	1	4	4
Total					4,248

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

In the **Federal Register** of January 12, 2005 (70 FR 2174), FDA requested comments for 60 days on the information collection. No comments were received on this information collection.

FDA estimates that, on average, approximately 8 products annually would be classified as serious and significant and thus require Medication Guides. FDA's regulatory impact analysis estimated that applicants would require approximately 2 months of full-time effort (320 hours) to develop (i.e., develop for submission to FDA for review and approval) each Medication Guide. Based on an average annual professional labor cost of $70,000, the cost of developing each Medication Guide would be approximately $11,666 for a total cost of $93,328.

In addition, FDA estimates that the sponsor of one of the new or supplementary applications will request an exemption from at least some of the Medication Guide format or content requirements. FDA estimates that this will entail approximately 4 hours of work, or about $200.

In addition, FDA estimates that two existing Medication Guides annually might require minor change under 21 CFR 314.70(b)(3)(ii) or 21 CFR 601.12(f), necessitating 3 days (72 hours) of full-time effort per Medication Guide, for a total of 144 hours or $5,250.

Under section 204.24(e) authorized dispensers are required to provide a Medication Guide directly to the patient (or the patient's agent) upon dispensing a product for which a Medication Guide is required. Thus, the final rule imposes a third-party reporting burden on authorized dispensers, who, for the most part, will be pharmacists. FDA estimates that, on average, it would take a pharmacist approximately 5 seconds (.0014 hour) to provide a Medication Guide to a patient.

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11267 Filed 6–6–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0202]

Draft Guidance for Industry on Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bar Code Label Requirements—Questions and Answers.'' FDA regulations require certain human drug and biological products to have on their labels a linear bar code that identifies the drug's National Drug Code (NDC) number. We have received several inquiries about how the requirements apply to specific products or circumstances. The purpose of the draft guidance is to respond to the questions.

DATES: Submit written or electronic comments on the draft guidance by August 8, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For products regulated by the Center for Drug Evaluation and Research: Michael D. Jones, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.