information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: *OPREinfocollection@acfjov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 28, 2008.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. E8–28656 Filed 12–3–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Interstate Referral Guide (IRG).

OMB No.: 0970–0209.

Description: The purpose of the Intergovernmental Referral Guide (IRG) project is to provide States, Foreign Nations and Tribes with an effective and efficient way of viewing and updating their profiles with child support enforcement policies and procedures, and their address and location code information by consolidating data available through numerous discrete sources into a centralized, automated repository.

Respondents: State IV–D Child Support Programs, Foreign Nation Child Support Programs and Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IRG State User Guide (Foreign Nations)	23	2	0.10	4.60
IRG Tribal User Guide	44	18	0.30	237.60
IRG State User Guide (States and Territories)	54	18	0.30	291.60

Estimated Total Annual Burden Hours: 533.80.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: December 1, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–28728 Filed 12–3–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0454]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substances Notification System

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 January 5, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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 Contact Substances Notification System—(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 when: (1) 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 (2) 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: (1) Information on the identity and the intended use of the food contact substance and (2) 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) specify the information that a notification must contain and require that: (1) A food contact notification (FCN) include FDA Form 3480 entitled ''Notification for New Use of a Food Contact Substance'' and (2) 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.

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to: (1) Establish that the proposed use of an indirect food additive is safe and (2) secure the publication of an indirect food additive regulation in parts 175 through 178 (21 CFR parts 175 through 178). Parts 175 through 178 describe the conditions under which the additive may be safely used.

In addition, FDA's guidance document entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations'' provides assistance to manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic. The recommendations in the guidance address the process by which manufacturers certify to FDA that their plastic products are safe for food contact.

Description of Respondents: Manufacturers of food contact substances.

In the **Federal Register** of August 27, 2008 (73 FR 50628), FDA published a 60-day notice requesting public comment on the information collection provisions. 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	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106 [2] (Category A)	FDA 3479	5	1	5	2	10
170.101 [3,7] (Category B)	FDA 3480	5	1	5	25	125
170.101 [4,7] (Category C)	FDA 3480	5	2	10	120	1,200
170.101 [5,7] (Category D)	FDA 3480	33	2	66	150	9,900
170.101 [6,7] (Category E)	FDA 3480	30	1	30	150	4,500
171.1 Indirect Food Additive Petitions		2	2	2	10,995	21,990
Guidance, ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations''		10	1	10	25	250
Total						37,975

[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 approximately five respondents will submit one notification annually for food contact substance formulations (Form FDA 3479), for a total of five responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 10 hours. 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. Thus, FDA estimates that five respondents will submit one such submission annually, for a total of five responses. FDA estimates the reporting burden to be 25.0 hours per response, for a total burden of 125 hours.

Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (denoted as Categories C, D, and E in 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. FDA estimates that five respondents will submit two Category C submissions annually, for a total of 10 responses. FDA estimates the reporting burden to be 120 hours per response, for a total burden of 1,200 hours. FDA estimates that 33 respondents will submit 2 Category D submissions annually, for a total of 66 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 9,900 hours. FDA estimates that 30 respondents will submit 1 Category E submission annually, for a total of 30 responses.

FDA estimates the reporting burden to be 150 hours per response, for a total burden of 4,500 hours.

FDA estimates that two respondents will submit one indirect food additive petition under § 171.1, for a total of two responses. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 21,990 hours.

FDA estimates that 10 respondents will utilize the recommendations in the guidance document entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. FDA estimates the reporting burden to be 25 hours per response, for a total burden of 250 hours.

Dated: November 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28694 Filed 12–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0607]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

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 reclassification petitions for medical devices.

DATES: Submit written or electronic comments on the collection of information by February 2, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Denver Presley, Jr.,Office Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Reclassification Petitions for Medical Devices—21 CFR Section 860.123 (OMB Control Number 0910–0138)—Extension

FDA has responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes, i.e., I, II, and III, to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use. Thus, the reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements. The reclassification petitions requesting classification from class III to class II or class I, if approved, provides an alternative route to the market in lieu of premarket approval for class III devices or from class I or II to one or the other class, which may increase requirements.

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