FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM

OMB No. 0910-0495

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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) specify the information that a notification must contain and 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. FDA accepts notifications for food contact substance formulations, submitted using Form 3479; notifications for food contact substance formulations are for a particular mixture of two or more food contact substances already authorized for the intended use, where the mixed components do not chemically react with each other to form new chemicals. FDA accepts food contact notifications for a previously unauthorized food contact substance, submitted using Form 3480.

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of an indirect food additive is safe and to secure the publication of an indirect food additive regulation in parts 175-178 (21 CFR parts 175-178) describing 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.

This is a request for OMB extension of the information collection requirements in FDA's guidance document entitled, "Use of Recycled Plastics in Food Packaging: Chemistry Considerations" and the following citations:

21 CFR 170.101 - Reporting –Information in a premarket notification for a food contact substance (FCN)
A notification for a food contact substance is required to contain information that provides a basis for estimating daily dietary exposure to the substance resulting from its notified use. Such a notification must also either contain data from toxicological studies which demonstrate that the daily dietary exposure to the food contact substance does not pose a safety hazard or must reference such data in FDA files. Information on the environmental impact that would result from the use and disposal of the proposed food contact substance must also be presented in the notification.

21 CFR 170.106 - Reporting – Notification for a food contact substance formulation (NFCSF)
A notification for a food contact substance formulation is required to contain information on the identity, amount, and intended effect of all substances in the formulation and information documenting that the intended use of each substance in the formulation is authorized.

We are also requesting OMB approval for the following forms which are used in collecting the information:

Form FDA 3479 - Notification for a Food Contact Substance Formulation (21 CFR 170.106)
Form FDA 3480 - Notification for New Use of a Food Contact Substance (21 CFR 170.101)

2. Purpose and Use of the Information Collection

Notifications for food contact substances and formulations submitted by manufacturers are reviewed by FDA scientific personnel to ascertain that the data establish the identity of the substance, establish its use in contact with food, and support the notifier's determination that the intended use in contact with food is safe. Section 409(h)(4) of the act requires FDA to keep confidential any information submitted in a premarket notification for the entire 120-day review period. If FDA does not object to the notification within 120 days after receipt, the notification becomes effective and the substance may be legally marketed. No action is required by FDA for a notification under section 409(h) of the act to become effective, and FDA is not required by statute to publish a notice that a notification is effective or to inform the notifier in writing that a notification has become effective.

3. Use of Improved Information Technology and Burden Reduction

FDA provides electronic Forms FDA 3479 and 3480 for notifers to use in submitting their notifications. The forms may be either printed and mailed, or, the template versions may be downloaded to the user's computer for data entry. Electronic copies of notifications must meet the requirements of part 11 and should be submitted to FDA on a CD-ROM or disk compatible with IBM-clone personal computers.

4. Efforts to Identify Duplication and Use of Similar Information

FDA continues to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. USDA has eliminated its approval processes for components of food contact materials that duplicated FDA's processes. In addition, the Food Quality Protection Act of 1996 gave sole jurisdiction to EPA for certain substances formerly regulated by FDA as food additives and by EPA as pesticide chemicals. Currently there is no significant duplication of data collection and evaluation for food contact substances among Federal agencies with jurisdiction. In addition, to avoid unnecessary duplication for individual submissions, existing data would be used whenever possible by FDA in evaluating notifications for food contact substances.

Because section 409(h)(4) of the act prohibits FDA from disclosing the information in a notification prior to the completion of the Agency's review, such information would not be available to other notifiers until FDA's review is complete. In addition, section 409(h)(2)(C) of the act permits only the manufacturer identified in the notification to rely on the notification to market legally the food contact substance. Therefore, the notification process will result in some duplication of review by FDA if a second manufacturer notifies the agency for the same use of the same food contact substance. In addition, the notification process for formulations that was requested by the regulated industry will also represent a small duplication of review. In order to minimize potential duplication of review, FDA expects to use an image based document management system to permit the agency to track effective notifications and to permit the agency to determine if a food contact substance has already been reviewed by the agency. FDA also expects to maintain a listing of effective notifications available on the agency's internet site.

5. Impact on Small Businesses or Other Small Entities

The premarket notification process for food contact substances may increase the burden on small businesses because small businesses will be required to notify FDA if they wish to manufacture a food contact substance, even if the food contact substance was the subject of a previous notification by another manufacturer. Previously, small businesses would have been able to rely on authorizations requested by other manufacturers under FDA's food additive petition process or threshold of regulation exemption process. Nevertheless, this increased burden will be minimal, because any information presented to support safety of the food contact substance in previous notifications will be available under the Freedom of Information Act (FOIA) after such previous notifications are effective.

The agency has established the types of data necessary to demonstrate that the use of a food contact substance is safe under 21 CFR 170.101 and that the components of a formulation are authorized under 21 CFR 170.106. In addition, FDA has developed guidance documents to assist potential notifiers in preparing notifications. Whenever possible, individual assistance will be given to requesters to minimize the likelihood that unnecessary work is performed. FDA aids small businesses in dealing with the requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

6. Consequences of Collecting the Information Less Frequently

Failure to provide requirements for notifications would prevent industry from preparing notifications sufficient to permit new products and would make Federal programs for notification review inefficient. Companies have a right, granted by law, to submit notifications for food contact substances in order to permit marketing of a food contact substance for a new use. Any restriction of this right would decrease the number of new food contact substances that could be legally marketed. In addition, FDA's acceptance of notifications for formulations will facilitate domestic and international trade in packaged foods and food contact materials.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Data collection for notifications for food contact substances involves no special circumstances. The requirements are consistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 27, 2008 (73 FR 50628). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA expects that notifications for food contact substances will often contain trade secret and commercial confidential information. Section 409(h)(4) of the act prohibits FDA from publicly disclosing information in a notification while it is under review by the Agency. Thereafter, only information that is releasable under the Freedom of Information Regulations (21 CFR Part 20) would be released to the public. This information is also safeguarded by Section 301(j) of the act.

A list of effective notifications will be available via the Agency's Internet site. This list includes the notifier, the identity of the food contact substance, the effective date of the notification, as well as any appropriate limitations on the use of the food contact substance. It does not include any confidential information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in the data requirements for notifications for food contact substances.

12. Estimates of Annualized Burden Hours and Costs

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	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	1	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 on 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 ten 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 two 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 one 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.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to respondents for completion and submission of food contact notifications to be approximately $8,734,250. Furnishing the information required even in a simple notification for a food contact substance requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. FDA estimates the average hourly wage for a team of professional employees to be approximately $115, which makes the annual wage cost for completion and submission approximately $4,367,125 (37,975 hours x $115 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $8,734,250.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

The annual cost to the government is $6.04 million dollars (including salaries and other costs).

15. Explanation for Program Changes or Adjustments

The increase in burden hours is due to the transfer of the burden hours associated with indirect food additive petitions from OMB Control No. 0910-0016 to this collection, as well as the addition of burden hours associated with the guidance document entitled, "Use of Recycled Plastics in Food Packaging: Chemistry Considerations." Capital costs and operating and maintenance costs decreased because $23 million was erroneously reported as capital costs or operating and maintenance costs in the previous submission.

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from this data collection will not be published. However, as noted

above, a list of effective notifications will be available via the Agency's Internet site. This list includes the notifier, the identity of the food contact substance, the effective date of the notification, as well as any appropriate limitations on the use of the food contact substance. It does not include any confidential information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The agency is not seeking to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A