Food Contact Substance Notification Program

0910-0495

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C 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 FD&C 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 FD&C 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 FD&C 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 substance notification (FCN) include a completed and signed Form FDA 3480 and (2) a notification for a food contact substance formulation include a completed and signed Form FDA 3479. These forms serve to summarize pertinent information in the notification. The forms facilitate both preparation and review of notifications because the forms 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.

Currently, interested persons transmit an FCN submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3480 whether it is submitted in electronic or paper format. FDA recently made minor revisions to Form FDA 3480 to better enable its use for electronic submission and to prompt FCN submitters to include certain information in a standard format. FDA estimates that the revisions to Form FDA 3480 will not change the amount of time necessary to complete the form.

In addition to its required use with FCNs, revised Form FDA 3480 is recommended to be used to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the agency, thus minimizing paperwork burden for food contact substance authorizations. FDA estimates that the amount of time for respondents to complete the revised Form FDA 3480 for these types of submissions will be 0.5 hours.

FDA has recently developed a new form, which the agency recommends be used with each submission of additional information (i.e. amendment) to an FCN submission currently under agency review, as well as be used to submit an amendment to a Pre-notification Consultation, or for an amendment to Master File in support of an FCN, whether submitted in electronic format or paper format. New Form FDA 3480A is titled, "Amendment to an Existing Food Contact Substance Notification, a Pre-Notification Consultation, or a Food Master File." The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format. Form FDA 3480A helps the respondent organize the submission to focus on the information needed for FDA's safety review.

FDA estimates that the amount of time for respondents to complete the new Form FDA 3480A will be 0.5 hours because the new form, used solely for transmitting an amendment, is much shorter than Form FDA 3480. Amendments include the following information on new Form FDA 3480A and in attachments to the form:

- Date of submission;
- Whether the notifier has determined that all files provided in an electronic transmission are free of computer viruses;
- Whether the submission is an amendment to an FCN submission, a pre-notification consultation, or a master file;
- The format of the submission (i.e., ESG, transmission on electronic physical media such as CD-ROM or DVD, or paper);
- The name of and contact information for the submitter, including the identity of the contact person and the company name (if applicable);
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the notifier; and
- A brief description of the information provided and the purpose(s) of the amendment.

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.

FDA requests OMB approval of Form FDA 3479 (which is unchanged); revised Form FDA 3480; new Form FDA 3480A; and the information collection provisions in the guidance entitled, "Use of Recycled Plastics in Food Packaging: Chemistry Considerations," and the following citations:

21 CFR 170.101 - Reporting

An FCN 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

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.

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.

Description of Respondents: The respondents are manufacturers of food contact substances sold in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Notifications for food contact substances and formulations contain summaries of data and narrative text. FDA currently accepts this information electronically via the Electronic Submission Gateway (ESG) or electronic media (such as: CD ROM, DVD). The agency estimates that all of the notifications (100%) will be submitted electronically in the next three years.

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 uses 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 maintains on the FDA Internet site a list of effective notifications.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. 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. We place on the FDA Internet site a list of effective notifications. 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.

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 complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. 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

There are no special circumstances associated with this collection of information.

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 April 2, 2012 (77 FR 19670). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any 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. As a result, all files are maintained in a secured area. Form FDA 3479, Form FDA 3480, and Form FDA 3480A, as well as their instructions, and related guidance, provide instructions for assisting FDA with protecting confidential information. A submitter may choose to provide a redacted copy of the notification, identifying that information that the submitter views as trade secret or as confidential commercial or financial information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

Section 409(h)(4) of the act prohibits FDA from publicly disclosing information in a notification while it is under review by the agency. After the review is complete and the FCN has become effective, we add it to the list of effective notifications on the FDA 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

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents are manufacturers of food contact substances sold in the United States.

12 a. Annualized Hour Burden Estimate

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

Table 1.Estimated Annual Reporting Burden[1]

21 CFR Section or other category	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden 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	N/A	1	1	1	10,995	10,995
Use of Recycled Plastics in Food Packaging: Chemistry Considerations	N/A	10	1	10	25	250
Pre-notification Consultation or Master File (concerning a food contact substance). [8]	FDA 3480	60	1	60	0.5	30
Amendment to an existing notification (170.101), amendment to a Pre-notification Consultation, or amendment to a Master File (concerning a food contact substance). [9]	FDA 3480A	50	1	50	0.5	25
Total						27,035

[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 Form FDA 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 Form FDA 3480.
[8] These notifications recommend the submission of Form FDA 3480.
[9] These notifications recommend the submission of Form FDA 3480A.

The forms in Table 1, and elements that would be prepared as attachments to the forms, may be submitted in electronic format via the ESG; e-mail, if appropriate; or may be submitted in paper format, or as electronic files on physical media with paper signature page. FDA expects that most if not all businesses filing these submissions in the next three years will choose to take advantage of the option of electronic submission. Thus, the burden estimates in Table 1 are based on the expectation of one hundred percent (100%) participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the revised or new forms and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

These estimates are based on FDA's experience with the food contact substance notification program. 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 will primarily consist of the manufacturer or supplier filling out Form FDA 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 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.

Based on the submissions received, FDA estimates that 60 respondents will submit information to a Pre-notification Consultation or a Master File in support of FCN submission using Form FDA 3480. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 30 hours.

Based on the submissions received, FDA estimates that 50 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, for an amendment to a pre-notification consultation, or for an amendment to a master file in support of an FCN. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 25 hours.

Based on the submissions received, FDA estimates that one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 10,995 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.

As noted, FDA estimates that all of the future Form FDA 3479, 3480, and 3480A submissions will be made electronically via the ESG. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20-$30.

12 b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. FDA estimates that the average hourly wage for these employees would be equivalent to a GS-14/Step-1 level in the locality pay area of Washington-Baltimore in 2012, approximately $50.41/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $100.82/hour. Thus, the overall estimated cost incurred by the respondents is $2,725,669 (27,035 burden hours x $100.82/hour = $2,725,668.70, rounded to 2,725,669). In addition, while FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20-$30.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

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

This is a revision in which the total number of responses is being increased and the total annual hour burden is being decreased. The total annual number of responses increased from 128 to 237 responses (an increase of 109 responses) and the total annual hour burden has decreased from 37,975 to 27,035 hours (a decrease of 10,940 hours).

Net Increase in the Number of Responses/Net Decrease in Hour Burden
The net increase in the number of responses was primarily due to the FDA's recommendation to use Form FDA 3480 for different uses (60 responses) and FDA's development of new Form FDA 3480A (50 responses) although we also reduced the responses in IC#6 (by 1 response). Thus, we are characterizing this increase in responses as a program change. Note, however, that the decrease of 1 response in IC#6 caused a large decrease in hour burden (a net decrease of 10,940 hours). Because the decrease of 1 response in IC#6 was based on the number of Indirect Food Additive Petitions received in the past three years, we are characterizing the decrease in hour burden (a net decrease of 10,940 hours) as an adjustment.

Table 3—Summary of Change in Responses and Hour Burden		
IC Number	Change in Responses	Change in Hour Burden
IC#1	No change	No change
IC#2	No change	No change
IC#3	No change	No change
IC#4	No change	No change
IC#5	No change	No change

Table 3—Summary of Change in Responses and Hour Burden		
IC#6	- 1	- 10,995
IC#7	No change	No change
IC#8	+ 60	+ 30
IC#9	+ 50	+ 25
Net Change	+ 109	- 10,940

For IC#6, we estimate that the respondents have decreased from 2 to 1, causing the annual number of responses to decrease by 1 and the annual hour burden to decrease by 10,995 hours. We are characterizing the decrease as an adjustment because it is based on the decrease in the number of Indirect Food Additive Petitions received by FDA in the past three years.

For IC#8, the increase in the number of responses (+ 60) was due to FDA's recommendation to use Form FDA 3480 to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN. We estimate that these uses will add 30 burden hours. We are characterizing this increase in the number of responses and burden hours as a program change.

For IC#9, the increase in the number of responses (+ 50) was due to FDA's recommendation to use new Form FDA 3480A with each amendment to an existing notification, amendment to a Pre-notification Consultation, or amendment to Master File in support of an FCN. We estimate that these uses will add 25 burden hours. We are characterizing this increase in the number of responses and burden hours as a program change.

16. Plans for Tabulation and Publication and Project Time Schedule

No statistics from the information obtained from this data collection will be published. However, as noted above in Section 10, a list of effective notifications is available on the FDA 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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.