Food Contact Substance Notification Program

OMB Control No. 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. In addition to its required use with FCNs, 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 recommends using Form FDA 3480A entitled, "*Amendment to an Existing Food Contact Substance Notification, a Pre-Notification Consultation, or a Food Master File*" for each submission of additional information (i.e., amendment) to an FCN submission currently under agency review. The form and elements 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.

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information respondents 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 is requesting, therefore, continued OMB approval for Form FDA 3479; Form FDA 3480; Form FDA 3480A; and the information collection provisions in the guidance entitled, "*Use of Recycled Plastics in Food Packaging: Chemistry Considerations*."

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 FD&C 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: Respondents to the information collection 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 October 8, 2015 (80 FR 60911). 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 FD&C 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 FD&C 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 to the information collection 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	10	2	20	2	40
170.101 [3,7] (Category B)	FDA 3480	6	1	6	25	150
170.101 [4,7] (Category C)	FDA 3480	6	2	12	120	1,440
170.101 [5,7] (Category D)	FDA 3480	42	2	84	150	12,600
170.101 [6,7] (Category E)	FDA 3480	38	1	38	150	5,700
Pre-notification Consultation or Master File (concerning a food contact substance). [8]	FDA 3480	190	1	190	0.5	95
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	100	1	100	0.5	50
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
Total						31,320

[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 estimates in Table 1 are based on our current experience with the food contact substance notification program and informal communication with industry.

Beginning in row 1, we estimate 10 respondents will each submit 2 notifications annually for food contact substance formulations (Form FDA 3479), for a total of 20 responses. We calculate a reporting burden of 2 hours per response, for a total of 40 hours. In row 2, we estimate six respondents. We believe the hourly burden for preparing these notifications will primarily consist of the manufacturer or supplier completing Form FDA 3480, verifying that a previous notification is effective, and preparing necessary documentation. We estimate one submission for each respondent, for a total of six responses. We calculate a reporting burden of 25 hours per response, for a total of 150 hours.

In rows 3, 4, and 5, we identify three tiers of FCNs that reflect different levels of burden applicable to the respective information collection items (denoted as Categories C, D, and E). We estimate 6 respondents will each submit 2 Category C submissions annually, for a total of 12 responses. We calculate a reporting burden of 120 hours per response, for a total burden of 1,440 hours. We estimate 42 respondents will each submit 2 Category D submissions annually, for a total of 84 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 12,600 hours. We estimate 38 respondents will each submit 1 Category E submission annually, for a total of 38 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 5,700 hours.

In row 6, we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours. Finally, in row 7, we estimate 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. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

In row 8, we estimate 190 respondents will each submit information to a prenotification consultation or a master file in support of FCN submission using Form FDA 3480. We calculate a reporting burden of 0.5 hours per response, for a total burden of 95 hours. In row 9, we estimate 100 respondents will each submit an amendment (Form FDA 3480A) to a substantive or nonsubstantive request of additional information to an incomplete FCN submission, an amendment to a prenotification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

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 2016, approximately $52.17/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly

cost to respondents to be $104.34/hour. Thus, the overall estimated cost incurred by the respondents is $3,267,928.80 (31,320 burden hours x $104.34/hour = 3,267,928.80, rounded to 2,820,831.90). 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 information collection reflects agency adjustments. The total annual number of responses increased from 237 to 461 responses (an increase of 224 responses) and the total annual hour burden increased from 27,035 to 31,320 hours (an increase of 4,285 hours). We attribute the increase to an increase in the number of respondents submitting reports. In turn, this increase caused the total annual hour burden to increase. Specific adjustments are as follows:

Table 2—Summary of Change in Responses and Hour Burden

IC Number	Change in Responses	Change in Hour Burden
IC#1	+15	+30
IC#2	+1	+25
IC#3	+2	+240
IC#4	+18	+2,700
IC#5	+8	+1,200
IC#6	No change	No change
IC#7	No change	No change
IC#8	+130	+65
IC#9	+50	+25
Net Change	+224	+4,285

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.