4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0294]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

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 Substance Notification Program--21 CFR 170.101, 170.106, and 171.1

OMB Control Number 0910-0495--Extension

This information collection supports FDA regulations regarding Food Contact Substance Notification, as well as associated guidance and accompanying forms. Section 409(h) of the Federal Food, Drug, and Cosmetic Act (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) we determine 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) we 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) includes Form FDA 3480 and (2) a notification for a food contact substance formulation includes 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 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.

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. We estimate that the amount of time for respondents to complete Form FDA 3480 will continue to be the same.

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 FDA, thus minimizing paperwork burden for food contact substance authorizations. We estimate that the amount of time for respondents to complete the Form FDA 3480 for these types of submissions is 0.5 hours.

FDA recommends using Form FDA 3480A for each submission of additional information (i.e., amendment) to an FCN submission of Pre-notification Consultation currently under Agency review, as well as for Master Files. Form FDA 3480A helps the respondent organize the submission to focus on the information needed for FDA's safety review. We estimate that the amount of time for respondents to complete the Form FDA 3480A for these types of submissions is 0.5 hours. The forms are available at https://www.fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs. To open field fillable forms, they must be downloaded and then opened from your local computer (not from a web browser).

FDA's guidance documents entitled: (1) "Preparation of Food Contact Notifications: Administrative," (2) "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations," and (3) "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" provide assistance to industry regarding the preparation of an FCN and a petition for food contact substances (FCSs). FDA also issued a guidance entitled, "Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk." The guidance provides assistance to industry regarding the preparation of an FCN for FDA review and evaluation of the safety of FCSs used in contact with infant formula and/or human milk. These guidances are available at

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/default.htm.

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 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: The respondents to this information collection are manufacturers of food contact substances sold in the United States. Respondents are from the private sector.

In the *Federal Register* of September 15, 2021 (86 FR 51358), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
170.106[2] (Category A)	3479	10	2	20	2	40
170.101[3, 7] (Category B)	3480	6	1	6	25	150
170.101[4, 7] (Category C)	3480	6	2	12	120	1,440
170.101[5, 7] (Category D)	3480	42	2	84	150	12,600
170.101[6, 7] (Category E)	3480	38	1	38	150	5,700

Pre-notification Consultation or Master File (concerning a food contact substance)[8]	3480	150	1	150	0.5 (30 minutes)	75
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]	3480A	80	1	80	0.5 (30 minutes)	40
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	65	1	65	25	1,625
Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk		2	1	2	5	10
Total						32,675

[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.

Based on a review of the information collection since our last request for OMB approval, we made adjustments to our burden estimate. The estimates are based on our current experience with the Food Contact Substance Notification Program and informal communication with industry.

Our estimated burden for the information collection reflects an overall increase of 1,345 hours and a corresponding decrease of 5 responses. We attribute this adjustment to a decrease in Pre-Notification Consultations or Master Files by 40 responses, a subsequent decrease of amendments to Pre-Notification Consultations or Master Files by 20 responses, and an increase of 55 respondents using the recommendations in the guidance document entitled "Use of Recycled Plastics in Food Packaging: Chemistry Considerations." As the average burden for

preparing recycling submissions is higher than for Pre-notification Consultations or Master Files, this results in an overall increase in total burden even with an overall decrease in responses.

Dated: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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