registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered. Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

The draft guidance document entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' (December 2014), which contained instructions for the proposed voluntary information collection, has recently been withdrawn. While notification of transfer of ownership information is not currently required, our medical device registration and listing website [1] communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

FDA estimates that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. FDA reached this estimate by identifying the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy, FDA estimates it will take respondents approximately 4 hours to establish the transfer of a 510(k) clearance.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators maintain a historical file containing the labeling and advertisements in use. The estimate for § 807.26 reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such records current.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify one importer and one person who imports or offers for import with readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. When they review the importer information annually, they simply verify the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,430 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Additionally, we have included non-substantive changes, incorporating the burden previously approved under OMB control number 0910–0852 into OMB control number 0910–0625, as approved by OMB in May 2021.

[1] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.*

Dated: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02600 Filed 2–7–22; 8:45 am]

BILLING CODE 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 March 10, 2022.

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.	Number of respondents	Number 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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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.

[FR Doc. 2022–02620 Filed 2–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on the National Health Service Corps

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on the National Health Service Corps (NACNHSC) will hold public meetings for the 2022 calendar year (CY). Information about NACNHSC, agendas, and materials for these meetings can be found on the NACNHSC website at: *https://www.hrsa.gov/advisory-committees/national-health-service-corps.*

DATES: NACNHSC meetings will be held on:

- March 29, 2022, 9:00 a.m.–5:00 p.m. Eastern Time (ET) and March 30, 2022, 9:00 a.m.–2:00 p.m. ET;
- June 28, 2022, 9:00 a.m.–5:00 p.m. ET and June 29, 2022, 9:00 a.m.–2:00 p.m. ET; and
- November 15, 2022, 9:00 a.m.–5:00 p.m. ET and November 16, 2022, 9:00 a.m.–2:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or ZOOM. For updates on how meetings will be held, visit the NACNHSC website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will be posted. In-person NACNHSC meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the meetings page on the NACNHSC website at *https://www.hrsa.gov/advisory-committees/national-health-service-corps/meetings.*

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official, Division of National Health Service Corps, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; phone (301) 443–3609; or *NHSCAdvisoryCouncil@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The NACNHSC consults with, advises, and makes recommendations to the Secretary of Health and Human Services with respect to the Secretary's responsibilities in carrying out *Subpart II,* Part D of Title III of the Public Health Service Act (42 U.S.C. 254d–254k), as amended, including the designation of areas of the United States with health professional shortages and assignment of National Health Service Corps (NHSC) clinicians to improve the delivery of health services in health professional shortage areas. Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. Refer to the meeting website listed above for any meeting updates.

For CY 2022 meetings, agenda items may include, but are not limited to, the identification of NHSC priorities for future program issues and concerns; proposed policy changes by using the varying levels of expertise represented on the NACNHSC to advise on specific program areas; updates from clinician workforce experts; and education and