assume wholesale distributors will expend 1 hour for each notification.

Because the extent of distribution of any illegitimate product will vary, we assume a wide distribution for each illegitimate product for purposes of establishing our burden estimate. We estimate that, for each notification that a manufacturer or repackager makes to FDA, the manufacturer or repackager will notify approximately 30 trading partners (relying on the number of distributors). This formula results in approximately 3,000 notifications annually to trading partners of manufacturers and repackagers. This estimate includes the notifications by manufacturers and repackagers who have determined that an illegitimate product is in their possession or control, as well as notifications by manufacturers who have determined that a product poses a high risk of illegitimacy.

We assume that a large wholesale distributor may have up to 4,500 trading partners, where a small wholesale distributor may have 200 trading partners, averaging approximately 2,350. We had originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, as a result of our experience with the collection and informal feedback from industry, we have lowered our estimate to reflect that 138 respondents will make 1,175 disclosures for a total of 162,150 disclosures annually and that each disclosure will require approximately 12 minutes, for a total of 32,430 hours annually.

We estimate that a pharmacy purchases prescription drugs from an average of two wholesale distributors. Therefore, a pharmacy would notify 2 trading partners for each of the 12 illegitimate products identified. This estimate results in in approximately 24 notifications annually to pharmacy trading partners.

We estimate that the burden for notifying trading partners of an illegitimate product and the number of trading partners notified will be the same as the estimates for notification of termination. The estimated total burden hours to notify trading partners that the notification is terminated is approximately 33,035 hours annually.

We assume a comparable amount of time is required to provide the information necessary for requesting to terminate a notification. The time required to investigate and resolve an illegitimate product notification will vary, but we assume that each notification will eventually be terminated. We assume that the number of requests for termination of a notification per year will be the same as the original number of notifications for a given year. The estimated total burden hours to make requests for termination of notifications to FDA is 250 hours annually.

Based on communications we have had with trading partners and stakeholders since the 2013 enactment of the DSCSA, we estimate that 20 trading partners or stakeholders will submit approximately 20 requests for a waiver, an exception, or an exemption. Also based on feedback from industry stakeholders, we estimate that respondents will expend an average of 80 hours to prepare and submit each request and to submit any additional followup information that we may request. We estimate the total burden as approximately 1,600 hours.

We estimate that we will receive from approximately one respondent approximately one notification or other information informing us that there has or has not been a material change in the circumstances that warranted the waiver, exception, or exemption and that each notification will require approximately 16 hours to prepare and submit to us. We estimate the total burden as approximately 16 hours.

We estimate that we will receive approximately one renewal request from approximately one respondent and that each request will require approximately 16 hours to prepare and submit to us. We estimate the total burden as approximately 16 hours.

Our estimated burden for the information collection reflects an overall increase of 56,116 hours and a corresponding increase of 271,638 responses annually. We attribute this adjustment to an increase in the number of illegitimate product notification submissions we received in the last couple of years and the number of such submissions we have received so far this fiscal year.

Dated: August 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19061 Filed 9–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

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 October 4, 2021.

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 0910–0511 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.

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

OMB Control Number 0910–0511—Revision

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug

Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health and FDA's Center for Biologics Evaluation and Research to initiate the administrative screening of new medical device applications and supplemental applications.

We are revising the information collection to add Form FDA 3601a, the ''Device Facility User Fee Cover Sheet.'' Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with FDA, a process known as establishment registration (21 CFR part 807, subparts A through D). (The information collection for medical device establishment registration and listing is approved under OMB control number 0910–0625.) All establishments required to register must pay a user fee. Form FDA 3601a, the ''Device Facility User Fee Cover Sheet,'' is designed to collect payments for the annual establishment registration fee for medical device establishments.

The total number of annual responses for Form FDA 3601 is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions and range from 5 to 30 minutes. For this analysis, we estimate 18 minutes per coversheet.

The total number of annual responses for Form FDA 3601a is based on the average number of cover sheet submissions received by FDA in recent years. Based on past FDA experience with various cover sheet submissions, we estimate 10 minutes per response.

In the **Federal Register** of June 12, 2020 (85 FR 35939), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, only one was responsive to the four collection of information topics solicited.

FDA's response to the comment is that the establishment registration fee is not eligible for a reduced small business fee. This can be found on our website at: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.*

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	6,182	1	6,182	0.30 (18 minutes)	1,855
3601a	24,086	1	24,086	0.17 (10 minutes)	4,095
Total			30,268		5,950

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 4,036 hours and a corresponding increase of 23,889 responses/records. We attribute these increases to two factors: We have revised the burden estimate to include Form FDA 3601a and we have adjusted the number of respondents for Form FDA 3601 to reflect our current data.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19113 Filed 9–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1857]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

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 October 4, 2021.

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 0910–0751. Also include the FDA docket number found in brackets in the heading of this document.