As reflected in table 1, row 6, we estimate 70 submissions under the PLAIR program. Since implementation of PLAIR there has been significant interest. We have therefore doubled our original estimate of 35 to 70 respondents annually but retain the average burden per response of 16 hours to provide the information recommended in the draft guidance.

Cumulatively these changes and adjustments result in a reduction in annual responses by 40,111,035 and an increase in burden hours by 130,572. These changes and adjustments reflect the realization of one-time burden associated with conforming to new CBP electronic reporting requirements since last OMB approval of the information collection that we believe no longer applies. Finally, we consolidated related information collection activities associated with CFR part 1, subparts D (§§ 1.70 through 1.81) and E (§§ 1.83 through 1.101) governing FDA import activities.

Dated: April 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08763 Filed 4–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to 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 May 26, 2020.

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 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Drug Supply Chain Security Act Implementation OMB Control Number 0910–0806—Revision

This information collection supports Agency implementation of section 582 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1) (FD&C Act) as revised by the Drug Supply Chain Security Act (DSCSA) (Pub. L. 113–54). For efficiency of Agency operations, we are revising information collection currently approved under OMB control number 0910–0806 pertaining to certain provisions of the DSCSA to also include information collection activity associated with waivers, exceptions, and exemptions from requirements. Finally, we are revising the title of the information collection from ''Identification of Suspect Product and Notification'' to ''Drug Supply Chain Security Act Implementation'' to reflect the broadening scope of this information collection request. As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources. We have developed guidance to assist respondents to the information collection with this topic and are including it in the information collection accordingly.

In the **Federal Register** of May 9, 2018 (83 FR 21297), we published a notice announcing the availability of a draft guidance for industry entitled ''Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act,'' including an analysis and inviting public comment under the PRA regarding the proposed information collection.

The draft guidance was issued consistent with FDA's good guidance practice regulation (21 CFR 10.115) which provides for public comment at any time. We intend to finalize the guidance document and are seeking OMB approval of the attendant information collection discussed in the document.

The most recent version of the draft guidance is available at: *https://www.fda.gov/media/113342/download.*

In the 2018 NOA, we estimated that annually 20 trading partners or stakeholders would submit approximately 20 requests for a waiver, exception, or exemption. This estimate was based on communications we had with trading partners and stakeholders since the 2013 enactment of the DSCSA. We also estimated that it would require an average of 40 hours for respondents to prepare and submit each request and to submit any additional followup information that we may request, for a total burden of approximately 800 hours.

As described in the draft guidance, a recipient of a waiver, exception, or exemption should notify us whenever there is a material change in the circumstances that is the basis for the relief. In addition, we intend to biennially review waivers, exceptions, and exemptions that extend longer than 2 years in duration and may ask the recipient to submit information to determine whether a material change in the circumstances has occurred. We estimated that annually we would receive approximately 1 notification or other information from approximately 1 respondent 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, for a total of approximately 16 hours.

A trading partner may request that we renew a waiver, exception, or exemption that is of limited duration. This request should include a detailed statement justifying the continuance of the relief and the desired length of the extension. We estimated that annually we would receive approximately 1 renewal request from approximately 1 respondent and that each request would require approximately 16 hours to prepare and submit to us, for a total of approximately 16 hours.

To address the comment that that it will require more than 40 hours to prepare and submit requests for a waiver, exception, or exemption from the requirements of section 582 of the FD&C Act and to submit any additional follow up information that we may request, we increased the estimate to 80 hours. Therefore, we now estimate that the total annual burden hours for submitting these requests is

approximately 1,600 hours, for a new total of 1,632 hours (table 1).

We have therefore adjusted our estimated burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests to FDA for a Waiver, Exception, or Exemption	20	1	20	80	1,600
Notifications to FDA of a Material Change in Circumstances Warranting the Waiver, Exception, or Exemption	1	1	1	16	16
Requests to FDA to Renew a Waiver, Exception, or Exemption	1	1	1	16	16
Total					1,632

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08766 Filed 4–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0278]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 23, 2020.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0278–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Information Collection Request Title: 0990–0278—Federalwide Assurance Form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting a three year extension of the Federalwide Assurance (FWA). The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Institutions engaged in human subjects research that is conducted or supported by HHS.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Federalwide Assurance (FWA)	14,000	2.0	30/60	14,000

Dated: April 20, 2020.

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–08702 Filed 4–23–20; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, May 12, 2020, 12:30 p.m. to May 13, 2020, 3:00 p.m., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817 which was published in the **Federal Register** on April 10, 2020, 85 FR 20285.

This notice is being amended to change the start time of the closed session on May 12, 2020, from 12:30 p.m. to 12:00 p.m. The closed session will now be held from 12:00 p.m. to 1:00 p.m. The meeting is partially closed to the public.

Dated: April 21, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–08779 Filed 4–23–20; 8:45 am]

BILLING CODE 4140–01–P