



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 [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 0910-0806. 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 Burden¹

Respondent Activity	No. of Respondents	No. 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.