



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2459]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

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 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 0910-0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@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.

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb-2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a webpage that includes contact and resource information pertaining to the RFDs process at <https://www.fda.gov/combination-products/jurisdictional-information>. As communicated on our webpage, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at combination@fda.hhs.gov.

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide

instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

- The guidance document entitled, “How to Write a Request for Designation” (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd>.
- The guidance document entitled “How to Prepare a Pre-Request for Designation,” (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd>.
- This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, “Requesting FDA Feedback on Combination Products,” (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products>.

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for

combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

In the *Federal Register* of July 31, 2023 (88 FR 49467), we published a 60-day notice soliciting comment on the proposed collection of information. One comment was received expressing interest in combination product submissions, but was not responsive to the four information collection topics solicited in our notice and therefore we do not discuss the comment here.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3.7; request for designation (RFD)	55	1	55	24	1,320
Pre-RFD submissions	77	1	77	24	1,848
CPAM requests	3	1	3	25	75
Total					3,243

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

Our estimated burden reflects a decrease in the number of respondents (four respondents) and a corresponding decrease in total hours (96 hours). Based on a recent evaluation of CPAM requests received from each product center in fiscal years 2020, 2021, and 2022, our estimated annual burden for CPAM requests remains unchanged.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

