E 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1108]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program

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 0910-0375. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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.

Third-Party Review Program

OMB Control Number 0910-0375--Extension

Section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directs FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 510(k) third party (3P510k) review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

Respondents to this information collection are businesses or government and can be for-profit or not-for-profit organizations, such as third party review organizations.

The guidance “510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations” (March 2020) was intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k program and third party review of Emergency Use Authorization (EUA) requests by describing FDA's expectations for the review of 510(k) submissions and EUA requests by third party review organizations. This guidance document also reflects section 523 of the FD&C Act, which directs FDA to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. This guidance was superseded on November 21, 2024, when FDA issued the final guidance “510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review

Organizations" (November 2024) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review*). The guidance also includes new content that outlines how FDA may contract with third party review organizations to perform reviews of EUA requests (3PEUA review) when appropriate emergency declaration authorities are active under section 564 of the FD&C Act. (See OMB Control Number 0910-0595.)

In the *Federal Register* of July 3, 2025 (90 FR 29552), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity; Guidance Document Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for accreditation (initial); Section V.D	1	1	1	40	40
Requests for accreditation (re-recognition); Section V. D	3	1	3	24	72
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	40	5,040
Complaints; Section V.C	1	1	1	0.25 (15 minutes)	0.25
Total					5,152.25

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity; Guidance Document Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section V. C	9	1	9	1	9
Recordkeeping system regarding complaints; Section V. C	9	1	9	2	18
Total					1,287

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

Upon review of this information collection, we have adjusted our burden estimate for the average burden hours required per response for initial requests for accreditation from 24 to 40 hours to more accurately reflect the time required based on recent experience of FDA program staff. This adjustment has resulted in an increase of 15 hours to the currently approved burden.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-20772 Filed: 11/21/2025 8:45 am; Publication Date: 11/24/2025]