4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2016-D-2565]

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 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 [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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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.

510(k) 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.

Respondents to this information collection are businesses or government, and can be for-profit or not-for-profit organizations.

The guidance "510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations" (March 2020) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program) is intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k review program. 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. 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.

In the *Federal Register* of June 24, 2022 (87 FR 37863), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although four comments were received, they were not responsive to the four collection of information topics solicited.

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[2]
Requests for accreditation (initial); Section VI	1	1	1	24	24
Requests for accreditation (re-recognition); Section VI	3	1	3	24	72
510(k) reviews conducted by accredited third parties; Section VI	9	14	126	40	5,040
Complaints; Section VII	1	1	1	0.25 (15 minutes)	1
Total					5,137

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

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; Section VII	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section VII	9	1	9	1	9
Recordkeeping system regarding complaints; Section VII	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.

Estimated Annual Recordkeeping Burden

510(k) reviews: The 3PROs should retain copies of all 510(k) reviews and associated correspondence. Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for 3P510k review to be 126 annually; approximately 14 annual reviews for each of the 9 3PROs. We estimate the average burden per recordkeeping to be 10 hours.

Records regarding qualifications to receive FDA recognition as a 3PRO: Under section 704(f) of the FD&C Act (21 U.S.C. 374(f)), a 3PRO must maintain records that support their initial and continuing qualifications to receive FDA recognition, including documentation of the training and qualifications of the 3PRO and its personnel; the procedures used by the 3P510k review organization for handling confidential information; the compensation arrangements made by the 3PRO; and the procedures used by the 3PRO to identify and avoid conflicts of interest. Additionally, the guidance states that 3PROs should retain information on the identity and

qualifications of all personnel who contributed to the technical review of each 510(k) submission and other relevant records. Because most of the burden of compiling the records is expressed in the reporting burden for requests for accreditation, we estimate the maintenance of such records to be 1 hour per recordkeeping annually.

Recordkeeping system regarding complaints: Section 523(b)(3)(F)(iv) of the FD&C Act requires 3PROs to agree in writing that they will promptly respond and attempt to resolve complaints regarding their activities. The guidance recommends that 3PROs establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours annually.

Based on our experience with the program since our last request for OMB approval, we have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden.

Dated: October 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-23377 Filed: 10/26/2022 8:45 am; Publication Date: 10/27/2022]