

510(k) Third-Party Review Program

OMB Control No. 0910-0375 -- Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

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.

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 This guidance was superseded on November 21, 2024, when FDA issued the final guidance "510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Guidance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" (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 Emergency Use Authorization (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.)

2. Purpose and Use of the Information Collection

The respondents for this information collection are public and private sector, for-profit and not-for-profit organizations, such as 3PROs. All respondents voluntarily enter into the program under which this information is collected.

The purpose of the program is: (1) to provide manufacturers of eligible devices with an alternative review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, individuals may apply for accreditation as third-party reviewers and, if accredited, must submit reports of their reviews to FDA.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 100% of respondents will submit 3P510k reviews and related information through the e-Copy Program. The guidance “eCopy Program for Medical Device Submissions” (April 2020) (available at <https://www.fda.gov/media/83522/download>) describes the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy improves the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. eCopies can be on a single CD, DVD, or flash drive. The guidance instructs the applicant to submit it to FDA, CDRH Document Control Center.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The number of respondents for this information collection who are small businesses (including non-profits) is approximately 67%. Participation in the third-party program is entirely voluntary.

FDA aids small business by providing guidance and information through the Division of Industry and Consumer Education (DICE) within the Center for Devices and Radiological Health (CDRH). DICE provides workshops, onsite evaluations and other technical and nonfinancial assistance to small manufacturers. We also maintain a toll-free telephone number, e-mail account, and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

Both requests for accreditation and 3P510(k) reviews are submitted once. There is no established frequency for the information collection under the third-party review program, so the consequences of collecting this information less frequently are minimal. There are no legal obstacles to reduce the burden.

The frequency of re-recognition is every (3 years), therefore we expect to receive approximately 3 re-recognition requests per year.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with the information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of July 3, 2025 (90 FR 29552), we published a 60-day notice requesting public comment on the proposed collection of information.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected is name, work address, work email address, work telephone number and occasionally work fax number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

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

Table 1.--Estimated Annual Reporting Burden¹

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 Burden¹

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.

Estimated Annual Reporting Burden

Requests for accreditation (initial): On average, the Agency has received one application for accreditation for 3P510k review per year. Upon review of this IC, we have adjusted our burden estimate for the average burden hours required per response upward from 24 hours 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 14 hours to the currently approved burden.

Requests for accreditation (re-recognition): Based on the current number of 3PROs and the frequency of re-recognition (3 years), we expect to receive approximately 3 re-recognition requests per year. We expect the average burden per response to remain at the currently approved estimate of 24 hours.

510(k) reviews conducted by accredited third parties: Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for 3P510k review to remain as 126 annually, or an average of 14 per respondent.

Complaints: The guidance recommends that the 3PRO should forward to FDA information on any complaint (e.g., whistleblowing) it receives about a 510(k) submitter that could indicate an issue related to the safety or effectiveness of a medical device or a public health risk. We expect to receive one forwarded complaint per year. Based on similar information collections, we estimate the average burden per complaint to be 0.25 hours (15 minutes).

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.

12b. Annualized Cost Burden Estimate

We assume the activities identified in 12a will be completed by Lawyers (occupation code 23-1011) (approximately 50% of tasks) and Paralegals (occupation code 23-2011) (approximately 50% of tasks). To estimate costs to respondents, we used mean wage rates from the U.S. Department of Labor’s Bureau of Labor Statistics National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm) (May 2024). We doubled these figures to account for benefits and overhead, and calculated the costs as follows:

Table 3. – Annualized Burden Costs¹

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	3,220	\$176	\$566,720
Paralegal	3,220	\$64	\$206,080
Total			\$772,800

¹ Figures rounded to the nearest whole dollar.

We therefore estimate a total annualized cost burden of \$772,800 (rounded to the nearest dollar).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital or operating and maintenance costs associated with the information collection.

14. Annualized Cost to the Federal Government

Costs to the government are limited to the time required to review applications for accreditation, 510(k) review reports, and complaints. The agency has determined that no additional costs of FTE's would be required to conduct such reviews.

Approximately 40 hours is required for federal employees to review the applications for accreditation, 510(k) review reports, and complaints, at a GS-14, step 10 employee (in the area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA) salary cost of \$86.83 dollars per hour ([Pay & Leave : Salaries & Wages - OPM.gov](#)). We doubled this figure to account for benefits and overhead to arrive at a fully loaded total cost of \$6,946.40 for all review activities.

15. Explanation for Program Changes or Adjustments

Based on our experience with the program since our last request for OMB approval, we have adjusted our burden estimate. We have increased our burden estimate for the average burden hours required per response for initial requests for accreditation from 24 hours 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. We made no other adjustments to our burden estimate.

The guidance "510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations" (March 2020) 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).

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.