U.S. Food and Drug Administration
510(k) Third-Party Review Program

OMB Control Number 0910-0375

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   Section 210 of FDAMA established section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m) directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program is entirely voluntary. A Third Party Review Organization (3PRO) wishing to participate will submit a request for accreditation to FDA. Accredited 3PROs have the ability to review a manufacturer's 510(k) submission for selected devices (21 U.S.C. 360). After reviewing a submission, the 3PRO will forward a copy of the 510(k) submission, along with the 3PRO's documented review and recommendation to FDA. 3PROs should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

   In the Federal Register of September 14, 2018 (83 FR 46742), FDA published a notice entitled "510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations; Availability." The notice announced the availability of the draft guidance entitled "510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations." The draft guidance was intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k Review Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the FDA Reauthorization Act of 2017 (FDARA), FDA was directed to issue draft guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an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 3PROs to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.
2. Purpose and Use of the Information Collection

   The respondents for this information collection are private sector, for-profit organizations.

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 the respondents requesting accreditation will do so electronically.

Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144). FDA implemented eCopy requirements on January 1, 2013, with the issuance of the final eCopy guidance (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf). The guidance describes how device companies must replace at least one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy program, as well as the technical standards for an eCopy, are described in the guidance. The eCopy requirements do not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR and, therefore, do not change the cost or hour burden. Therefore, FDA further estimates that approximately 100% of the respondents will use electronic means to fulfill the agency's requirement for 510(k) reviews.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the collection of information required under the third-party review program. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Businesses or Other Small Entities

The number of respondents for this information collection who are small businesses is approximately 78%. Participation in the third-party program is entirely voluntary. As such, there is potentially no impact on small businesses unless they elect to participate in the program.

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 accreditation respondents and 510(k) reviews are submitted once under the information collection. Also, there is no established frequency for the information collection under the third-party review program, so consequences of collecting this information less frequently are minimal. There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of information.

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

On September 14, 2018 (83 FR 46742), FDA published a notice of availability of the guidance document entitled "510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations; Availability." The notice requested comment on the draft guidance and related revision of the information collection in OMB control number 0910-0375. We describe and respond below to the comments related to the information collection. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

(Comment 1) One comment suggested that the 3P510k Review Program reduces the burden for FDA staff and industry and increases the burden on patients and doctors to figure out which devices are safe and which are not.

Another comment suggested that FDA has not demonstrated that its proposed changes to the 3P510k review program will benefit patients and that the 3P510k Review Program reduces patient safety, rather than protecting patients from potentially harmful devices.

(Response 1) FDA disagrees with these comments. Section 523 of the FD&C Act requires FDA to accredit persons for the purpose of reviewing reports submitted under section 510(k) and making a recommendation to the FDA (21 U.S.C. 360m). All devices subject to the 510(k) requirements, including devices cleared through the 3P510k Review Program, must demonstrate substantial equivalence to a legally marketed device prior to introduction into interstate commerce (see 21 U.S.C. §§ 360(k), 360(n), 360c(f)(1) & 360c(i); 21 CFR 807.92(a)(3)). Under the 3P510k Review Program, the objective is for the 3PRO to provide a review equivalent to that of an FDA reviewer, including making a recommendation, which it submits to FDA. FDA reviews that information in order to make a final determination of substantial equivalence and where appropriate, FDA will limit its review to a supervisory-level review. Therefore, the burden to demonstrate substantial equivalence remains unchanged.
In addition, this guidance describes the factors FDA will use to ensure only appropriate device types are eligible for the 3P510k Review Program and benefits the public health

by allowing new, low-to-moderate risk devices to obtain FDA-equivalent review while enabling FDA to focus more resources on higher risk and more complex devices that necessitate more rigorous review benefitting the public health. Accordingly, no change to the guidance is necessary.

(Comment 2) One comment suggested that the proposed definition of a 510(k) Submitter is too narrow by referring to "scientific and technical data" and should be revised to reflect the additional components of a 510(k) submission, such as intended use.

(Response 2) FDA agrees that a 510(k) submission can include more than scientific and technical data. Rather than trying to define the appropriate components of a 510(k) submission in this guidance, FDA has modified the definition of 510(k) Submitter by removing reference to submitting "scientific and technical data."

(Comment 3) One comment requested clarification regarding to whom the 3PROs should provide copies of written communications between the 510(k) Submitter and the 3PR O and, if these copies are submitted to FDA, that this is unnecessarily burdensome to both the 510(k) submitter and the 3PRO.

(Response 3) FDA agrees that this language should be, and therefore it has been, clarified as FDA's intent was that these communications would be provided to FDA and that the context of these communications is the communication and response to deficiencies in the submission. However, FDA disagrees that providing the Agency this information is unnecessarily burdensome. FDA believes that in order to understand and evaluate whether the 3PRO conducted an FDA-equivalent review, it is necessary to understand how the 3PRO documented and communicated any deficiencies it found during its review, how the 510(k) Submitter responded to those deficiencies, and how the 3PRO evaluated those responses.

(Comment 4) Several comments suggested that the language in the guidance is unclear as to whether the 510(k) Submitter should provide the 3PRO with all subsequent correspondence that the Submitter has with FDA and that once a 3PRO has submitted its recommendation to FDA that any substantive interactions between the FDA and the 510(k) submitter are not always relevant and any mandate to supply such correspondence creates additional burden.

Additionally, a comment requested clarification regarding to whom the 3P organization should provide a copy of all written communications.

(Response 4) To the extent that the commenter refers to subsequent correspondence on the 510(k) submission in question, FDA disagrees with the comment. The 3PRO's responsibilities to provide an FDA-equivalent review do not end with the initial submission to FDA. As discussed in subsection VI.J of the guidance, FDA will contact the 3PRO by telephone or email if additional information is needed. FDA not only expects the 3PRO to communicate with the 510(k) Submitter to resolve any issues needing the Submitter's input, FDA also expects the 3PRO to thoroughly evaluate any

responses received and to document those in its updated review memo. Therefore, the 3PRO should be involved in any discussions between the FDA and the 510(k) Submitter regarding the request for additional information. FDA does not believe that the continued involvement of the 3PRO creates an unnecessary burden given their responsibilities, whereas their involvement in those discussions ensures the response is evaluated in a timely and efficient manner.

(Comment 5) One comment requested clarification on what should a new review memo provided by 3PRO in response to FDA's request for additional information include or if a documented evaluation result referring to the evaluation of the 510(k) Submitters responses to FDA's request for additional information is sufficient.

(Response 5) FDA has clarified in the final guidance that the initial review memo provided by the 3PRO should be updated with this new information in response to FDA's request for additional information. This is consistent with the FDA's expectation that the 3PRO provide a review equivalent to that of an FDA reviewer.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or other data of a personal nature. 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 submitted is name, telephone number, email address, work address, and fax number of the contact person. For foreign organizations name, address, telephone number, email address, and fax number of an authorized representative located within the United States is collected. This ICR is directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s).

FDA further 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 routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

Information regarding Accredited Third Parties, and review reports by Accredited Third Parties are available under the Freedom of Information Act and 21 CFR part 20. Data will be kept private to the extent allowed by the law.

11. Justification for Sensitive Questions

The information does not include questions about sexual behavior and attitudes, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Estimated Annual Reporting Burden

Requests for accreditation (initial): On average, the Agency has received one application for accreditation for 3P510k review per year. There is no change to this information collection (IC) from the currently approved burden estimate.

Requests for accreditation (re-recognition): We have added an IC for re-recognition requests to be consistent with the guidance, which states that requests for re-recognition will be handled in the same manner as initial recognition requests. Based on the estimated number of 3PROs (7) and the frequency of re-recognition (3 years), we expect to receive approximately 2 re-recognition requests per year. We expect the average burden per response to be the same as an initial request (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 third-party review to be 147 annually; approximately 21 annual reviews for each of the 7 3PROs. This IC has been adjusted based on current trends, however, there is no program change to this IC.

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. Therefore, we have added an IC for complaints to the reporting burden. 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).

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Requests for accreditation (initial)	1	1	1	24	24
Requests for accreditation (rerecognition)	2	1	2	24	48
510(k) reviews conducted by accredited third parties	7	21	147	40	5,880
Complaints[4]	1	1	1	0.25	1
Total					5,953

[1] Totals have been rounded.

[2] There is no change to this IC from the currently approved burden estimate.

[3] This IC has been adjusted based on current trends, however, there is no program change to this IC.

[4] This IC revises OMB control number 0910-0375 to reflect the draft guidance entitled "510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations."

Estimated Annual Recordkeeping Burden

510(k) Reviews: 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 147 annually; approximately 21 annual reviews for each of the 7 3PROs. We estimate the average burden per recordkeeping to be 10 hours. The estimated number of records and recordkeepers have been adjusted based on current trends, however, there is no program change to this IC.

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. Therefore, we have added an IC for "Records regarding qualification to receive FDA recognition as a 3PRO." 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)(E)(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. Therefore, we have added an IC for "Recordkeeping system regarding complaints." Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours.

Table 2.--Estimated Annual Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510(k) reviews[1]	7	21	147	10	1,470
Records regarding qualifications to receive FDA recognition as a 3PRO[2]	7	1	7	1	7
Recordkeeping system regarding complaints[2]	7	1	7	2	14
Total					1,491

[1] This IC has been adjusted based current trends, however, there is no program change to this IC.

[2] This IC revises OMB control number 0910-0375 to reflect the draft guidance entitled "510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations."

12b. Annualized Cost Burden Estimate

There are no costs imposed by this program, as it is a voluntary program intended to provide manufacturers with an alternative path of review. The cost of conducting reviews and submitting reports will be charged by accredited third-parties to manufacturers who choose to participate in the program, but such cost is not established by the program.

A 3PRO may assess a reasonable fee for their services. The fee for a 510(k) review is a matter to be determined by contract between the 3PRO and the submitter. Although FDA is not aware of the average fee for 510(k) review conducted by a 3PRO, we believe it to be close to the standard user fee imposed by the FDA for conducting a 510(k) review.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

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

Approximately 35 hours is required to complete a 510(k) review report. At a GS-14, step 10 employee (in the area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA) salary cost of $73 dollars per hour (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/19Tables/html/DCB_h.aspx), the total cost is $2,555.

15. Explanation for Program Changes or Adjustments

    We revised our estimates by adding new ICs, changing the title of the ICR, and adjusting the existing ICs based on current trends. Despite the addition of new ICs, the estimated burden reflects an overall decrease of 5,580 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

    No publication of information for statistical use is planned.

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

    FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.