

Medical Device Accessories

OMB Control No. 0910-0823 – EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance. FDA has jurisdiction over accessories to medical devices because the definition of the term “device” provided in Section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) defines “device” to include, among other things, an “accessory.”

FDA has traditionally determined the classification of device accessory types in one of two ways: First, by inclusion in the same classification as the parent device, which can be: (1) through operation of 510(k) Premarket Notification clearance, (2) through operation of Premarket Application (PMA) approval, or (3) by express inclusion in the classification regulation or reclassification order for the parent device; and second, by issuance of a unique, separate classification regulation for the accessory.

Section 513(f)(6) of the FD&C Act (21 U.S.C. 360c(f)(6)), provides mechanisms for requesting the appropriate classification (or reclassification) of: (1) an accessory that is “included in an application for premarket approval ... under section 515 or a report under section 510(k) for clearance of such device [intended to be used with the accessory] and the Secretary has not classified such accessory distinctly from another device,” and (2) an accessory “that [has] been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a request for classification under [513(f)(2)].”

FDA’s guidance document “Medical Device Accessories--Describing Accessories and Classification Pathways” (the Accessories guidance, December 2017) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways>) is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA’s policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA generally considers an “accessory” and describes the processes under section 513(f)(6) of the FD&C Act to allow requests for risk- and regulatory control-based classification of accessories.

While other mechanisms exist to request the appropriate classification of an accessory¹, the Accessories guidance focuses on the Accessory Classification process described in section 513(f)(6) of the FD&C Act, which requires that FDA, upon request, classify existing and new accessories notwithstanding the classification of any other device with which such accessory is intended to be used. This means that the classification of an accessory may not be the same as its parent device, depending on the risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and effectiveness of the accessory. Until an accessory is distinctly classified, its existing classification will continue to apply.

For both Existing and New Accessory Requests, manufacturers must request proper classification of their accessory in the submission and include draft special controls, if requesting classification into class II. The processes that we use to classify an accessory are like those used for De Novo requests. If FDA grants the Accessory Request, FDA must issue an order establishing a new classification regulation for the accessory type. If FDA denies the Accessory Request, FDA must issue a letter with a detailed description and justification for our determination.

We are therefore requesting OMB approval for the information collection provisions set forth in 513(f)(6) of the FD&C Act (21 U.S.C. 360c(f)(6)) governing requests for risk- and regulatory control-based classification of accessories and associated agency guidance as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA medical, scientific, regulatory, and engineering staff uses the information to make determinations as to whether or not devices have been determined to provide reasonable assurance of the safety and effectiveness of the device and can, therefore, be allowed to enter the U.S. market. The information also allows accessories to be classified separately from their parent device, thereby potentially reducing the regulatory burden on industry for accessories which do not carry the same level of risk as the parent device. The submission review process allows for scientific and/or medical review of devices to confirm that devices are safe and effective. This review process prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. Additionally, if this information were not collected, there would be a negative impact on industry, as there would continue to be unnecessary regulatory burden for accessories which pose a lower risk than their parent device.

3. Use of Improved Information Technology and Burden Reduction

¹ For example, for a new accessory type (i.e., an accessory of a type that has not been previously classified under the FD&C Act, cleared for marketing under a 510(k) submission, or approved in a PMA), the De Novo classification process under section 513(f)(2) may be used to obtain classification of such an accessory. In addition, manufacturers of accessories within an accessory type that has already been classified by regulation or order, or has received PMA approval or 510(k) clearance, may seek reclassification or exemption from the requirement to submit a 510(k) notification under applicable sections of the FD&C Act. The information collected for an accessory classification De Novo request is substantially the same as a De Novo request, is submitted in the same manner, and has the same estimated information collection burden. The burden estimate associated with “De Novo request under 21 U.S.C. 513(f)(2)(i)” and “De Novo request under 21 U.S.C. 513(f)(2)(ii),” in OMB control number 0910-0844, includes De Novo requests for accessories.

FDA estimates that 100% of respondents will submit both Existing and New Accessory Requests 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. 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.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

The information related to submissions for accessories may, in some cases, overlap with information previously included in a related 510(k) submission or PMA for the medical device. Wherever possible, FDA will not require that this information be re-submitted but instead may rely on the 510(k) submission or PMA as reference. Therefore, duplication with other data sources available to FDA is expected to be minimal.

5. Impact on Small Businesses or Other Small Entities

Using the guidelines set by the Small Business Administration on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments are considered small businesses.

FDA aids small business by providing guidance and information through the Division of Industry and Consumer Education (DICE) within the 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

Respondents will respond to the data collection occasionally when they elect to apply for distinct classification of a new or existing accessory. Applicants determine when a product will be submitted for an accessory classification request. If the information were collected less frequently, or not collected, FDA could not ensure that the devices are reasonably safe and effective for their intended use. Additionally, these devices may continue to carry a higher regulatory burden than necessary if this information were not collected.

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 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 June 16, 2025 (90 FR 25326), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 submitted is point of contact name, work address, work email address, work telephone number, and 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 Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA 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

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

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Existing Accessory Request	10	1	10	40	400
New Accessory Request	5	1	5	40	200
Total					600

Respondents are medical device manufacturers seeking to market device accessories submitting requests for risk- and regulatory control-based classification of accessories under section 513(f)(6) of the FD&C Act. Based on recent trends, we expect to receive approximately 10 Existing Accessory Requests and 5 New Accessory Requests per year. FDA administrative and technical staff, who are familiar with the requirements for submission of accessory classification requests under section 513(f)(6) of the FD&C Act, estimate that it takes an average of 40 hours to prepare and submit both Existing and New Accessory Requests.

12b. Annualized Cost Burden Estimate

We assume the activities identified in *Question-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 2023). We doubled these figures to account for benefits and overhead, and calculated the costs as follows:

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (mean) hourly wage for occupation code 23-1011) May 2023. https://www.bls.gov/oes/current/oes_nat.htm.

Table 3. – Annualized Burden Costs¹

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	300	\$170	\$51,000
Paralegal	300	\$64	\$19,200
Total			70,200

¹ Figures rounded to the nearest whole dollar.

We therefore estimate a total annualized burden cost of \$70,200.

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

We estimate an average allocation of 20 full time equivalent (FTE) employees, consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for review and processing of accessory classification requests. Assuming a cost of \$364,544.58 per position (which is the agency’s projected average cost of an FTE including benefits*), we estimate an annual cost to the Federal government of \$7,290,892 (\$364,544.58 x 20 FTEs, rounded).

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2024 as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Based on our experience with the program since our last request for OMB approval, we have made no adjustments to our burden estimate.

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.