Medical Device Accessories

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA has jurisdiction over accessories 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[1] or reclassification order[2] for the parent device; and second, by issuance of a unique, separate classification regulation for the accessory.

The guidance document "Medical Device Accessories--Describing Accessories and Classification Mechanisms for Accessory Types" clarifies how its risk- and regulatory control-based classification framework applies to accessory devices and discusses the mechanisms by which FDA, manufacturers, or other parties may seek the risk- and regulatory control-based classification of accessory types. Specifically, this guidance encourages manufacturers and other parties to utilize the *de novo* classification process under Section 513(f)(2) of the FD&C Act to request risk and regulatory control-based classifications of accessories of a new type. This process provides a pathway to Class I or Class II classification for accessories for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. In addition, this guidance provides a discussion of mechanisms whereby an interested party may request risk- and regulatory control-based classification of an accessory that was included under the approval of a PMA for the corresponding parent device (OMB control number 0910-0120 and 0910-0138). Finally, the guidance document provides guidance for how interested parties may seek a reclassification of a previously classified accessory (OMB control number 0910-0138).

The guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB)

[1] See Section 513(d) of the FD&C Act.

[2] Two reclassification processes are described in Section 513(e) and 513(f)(3) of the FD&C Act. Prior to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), FDA reclassified devices under Section 513(e) of the FD&C Act through rulemaking; FDASIA changed this to an order process.

under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 860, subpart C, have been approved under OMB control number 0910-0138. The collections of information in the guidance document titled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" has been approved under OMB control number 0910-0756 and the guidance documents titled "Guidance for Industry and Food and Drug Administration Staff - User Fees for 513(g) Requests for Information" and "FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act - Guidance for Industry and Food and Drug Administration Staff" have been approved under OMB control number 0910-0705.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The information collected in a de novo submission is used by the medical, scientific, regulatory, and engineering staffs of FDA in making 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. If the information were not collected, the impact to the Federal program would be negligible. The impact, however, to the public health of the U.S. would be great. The de novo submission review process allows for scientific and/or medical review of devices, under 513(f)(2) of the FD&C Act, to confirm that the new devices are safe and effective. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

Respondents to this information collection are Private Sector for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

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.

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

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 *de novo* 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 in dealing with the requirements of the regulations by providing guidance and information through the Division of Industry and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the data collection occasionally when they elect to apply for premarket approval of a device in a de novo submission. Applicants determine when a product will be submitted for premarket approval. 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.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 01/20/2015 (80 FR 2710). We received a total of 12 comments on the guidance. Of these the following were related to the information collection:

Two commenters raised concerns regarding the possible difficulties for manufacturers to submit a de novo for new accessories and for risk- and regulatory control-based classification of accessories that were approved under the PMA for the parent medical devices. One comment questioned whether FDA considered the possible "practical and economic impact" of the proposed definition of "accessories" that may result in manufacturers being obligated to list some components as accessories for FDA's registration and listing process. The second comment anticipates that "few companies are likely to pursue this route given the associated costs and minimal advantage in time to market." Neither comment specifically discusses the potential PRA burden hours of voluntarily submitting a de novo application; however, it may be inferred that this could impact their resources under PRA for submitting a de novo.

Also, FDA is not proposing to limit or remove any mechanism that currently exists for manufacturers to obtain marketing authorization for accessories. De novos are typically less burdensome than PMAs for the purpose of classifying a new accessory. Furthermore, if a manufacturer wishes for an accessory to remain in the same regulatory class as the parent device, that manufacturer may continue to submit the accessory for clearance or approval under the submission type applicable to the parent device.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is given to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of information submitted to FDA under a premarket submission is governed by the provisions of 21 CFR part 20. These provisions do not permit disclosure of information that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR part 20. Data will be kept private to the fullest extent allowed by law.

11. Justification for Sensitive Questions

The information does not include questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Respondents are medical device manufacturers seeking to market device accessories. Of the approximately 41 de novo applications received per year, only two have been associated with accessories. With heightened awareness of the availability of the de novo pathway for accessories, we expect to receive four to six additional accessories applications per year. Therefore, we estimate that we will receive approximately eight accessory classification de novo requests per year. Based on estimates by FDA

administrative and technical staff who are familiar with the proposed submission process for accessory classification requests and on our burden estimate for a similar information collection request (see "De Novo Classification Process Evaluation of Automatic Class III Designation; Draft Guidance for Industry and Food and Drug Administration Staff; Availability," 79 FR 47651 at 47653, August 14, 2014), we estimate that the submission process for each accessory classification request will take approximately 180 hours.

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

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Accessory classification *de novo* request	8	1	8	180	1,440

12b. Annualized Cost Burden Estimate

FDA estimates that the total estimated burden cost to industry relating to this information collection will be $87,840, which is the total number of burden hours expended, 1,440, multiplied by an average wage rate of $61 per hour.*

* Based on The Regulatory Affairs Professional Society (RAPS) overall base annual compensation of $126,163 for a U.S. regulatory affairs professional (http://www.raps.org/news-trends/scope-of-practice/2014/). The hourly rate of $61 above assumes a 40-hour work week and is rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory affairs professional	1,440	$61.00	$87,840

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

FDA estimates that approximately 33.5 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for review and processing of de novo submissions for accessories. An average full time equivalent (FTE) employee is projected to cost FDA/CDRH $283,487,* which consists of the employee's salary and any overhead which accompanies that employee. The burden to government of this information collection is $9,496,815** per year ($283,487 x 33.5 FTEs).

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).
** Rounded

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

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

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.