U.S. Food and Drug Administration
Medical Device Accessories
OMB Control Number 0910-0823

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.

FDA's guidance document "Medical Device Accessories--Describing Accessories and Classification Pathways" (the Accessories guidance) 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 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)) to allow requests for risk- and regulatory control-based classification of accessories.

We are requesting OMB approval to revise this information collection request (ICR) by adding burden estimates for two new accessory classification pathways created by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52).

FDARA changed how FDA regulates medical device accessories. Specifically, section 707 of FDARA added section 513(f)(6) to the statute and 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

[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.

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. This provision does not preclude a manufacturer from submitting a De Novo request for an accessory.

When the Accessories guidance originally issued, FDA encouraged the use of the De Novo classification process to allow manufacturers to request risk- and regulatory control-based classification of accessories of a new type. FDA's recommendations in the guidance represented a new information collection as an accessory classification De Novo request. The information collected for an accessory classification De Novo request is substantially the same as a De Novo request (since approved under OMB control number 0910-0844), 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. We have determined that the burden estimate for "Accessory Classification De Novo Requests" in this ICR (Accessory Classification Requests; OMB control number 0910-0823) is redundant and have, therefore, removed it.

Depending on an accessory's regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k), pre-market application (PMA), or De Novo request (approved under OMB control numbers 0910-0120, 0910-0231, and 0910-0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate classification through a new stand-alone premarket submission (Existing Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as "Q-submissions" (approved under OMB control number 0910-0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA, or De Novo request. Manufacturers may include new accessories into a 510(k) or PMA with the parent device (New Accessory Request). New Accessory Requests will have the same deadline as the 510(k) or PMA. Therefore, new accessory types should follow the applicable Medical Device User Fee Amendments of 2017 deadline for the parent submission. The decision for New Accessory Requests will be separate from the decision for the marketing application.

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

will be 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.

2. Purpose and Use of the Information Collection

The information 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 submission review process allows for scientific and/or medical review of devices 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 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 04/04/2019 (84 FR 13296). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is given to respondents.

10. Assurance of Confidentiality Provided to Respondents

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). The PII submitted via the coversheet is name, address, email address, telephone number and occasionally a fax number.

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.

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. We expect to receive approximately 15 Existing Accessory Requests and 10 New Accessory Requests per year. Based on estimates by FDA administrative and technical staff who are familiar with the submission process for accessory classification requests, we estimate that the "Average Burden per Response" for both Existing and New Accessory Requests will be approximately 40 hours per submission.

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 |
|---|---|---|---|---|---|
| Existing Accessory Request | 15 | 1 | 15 | 40 | 600 |
| New Accessory Request | 10 | 1 | 10 | 40 | 400 |
| Total | | | | | 1,000 |

12b. Annualized Cost Burden Estimate

FDA estimates that the total estimated burden cost to industry relating to this information collection will be $72,000, which is the total number of burden hours expended, 1,000, multiplied by an average wage rate of $72 per hour.*

* The estimated wage rate for a Regulatory Affairs Professional is based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of $150,422 for a U.S. regulatory affairs professional (https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, p. 11, accessed 10/26/18). The hourly wage rate of $72 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 | 1,000 | $72.00 | $72,000 |

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. Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including benefits*), the estimated annual Federal cost is $9,055,218.**

    *Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.
    ** Rounded

15. Explanation for Program Changes or Adjustments

    Our estimated burden for the information collection reflects an overall decrease of 440 hours and an increase of 17 responses. Factors contributing to the revision of the burden estimate include the addition of the two new accessory classification pathways crated by FDARA and the removal of redundant burden described earlier in this document.

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 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.