4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0823. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Accessories

OMB Control Number 0910-0823--Extension

FDA's guidance document "Medical Device Accessories--Describing Accessories and Classification Pathways" (the Accessories guidance)[1] 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 risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and

[1] The guidance document is available on FDA's website (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429672.pdf).

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.

In the *Federal Register* of April 4, 2019 (84 FR 13296), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

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

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

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 created by FDARA and the removal of redundant burden described earlier in this document.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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