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 (the PRA).

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-NEW and title "Medical Device Accessories." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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-NEW

The draft guidance encourages manufacturers and other parties to utilize the process defined in section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to request risk- and regulatory control-based classifications of new types of accessories. This process provides a pathway to class I or class II classification for accessory devices 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 accordance with section 513(f)(2) of the FD&C Act, manufacturers and other parties may submit a de novo requesting FDA to make a classification determination for the accessory device according to the criteria in section 513(a)(1) of the FD&C Act. The de novo must include a description of the device and detailed information and reasons for any recommended classification (see section 513(f)(2)(A)(v) of the FD&C Act).

In the **Federal Register** of January 20, 2015 (80 FR 2710), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received a total of 12 comments on the guidance. Of these the following were related to the information collection:

Two comments 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 premarket approval application (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 the 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.

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
Accessory classification de novo request	8	1	8	180	1,440

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

Respondents are medical device manufacturers seeking to market device accessories. Of the approximately 41 de novo applications received per year, only 2 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.

The draft guidance also refers to previously approved collections of information found in FDA regulations. 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.

Dated: June 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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