recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: January 9, 2015.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–00699 Filed 1–16–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0025]

Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types.'' This draft document provides proposed guidance to industry and FDA staff about the regulation of accessories in medical devices. The guidance explains what FDA considers to be an ''accessory,'' outlines how the risk-based framework for the classification of devices applies to accessories, and describes the use of the *de novo* classification process for the classification of new types of accessories. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 20, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 23, 2015. See section IV of this document, the ''Paperwork Reduction Act of 1995.''

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance or the information collection to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sugato De, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5435, Silver Spring, MD 20993–0002, 301–796–6270 or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document is intended to provide guidance to industry and FDA staff about the regulation of accessories to other medical devices. In doing so, this guidance document explains what FDA considers to be an ''accessory'' and outlines how the risk-based framework for the classification of devices applies to accessories. In addition, this guidance describes use of the *de novo* classification process to classify new types of accessory devices under Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)) based on risk and the ability of general and special controls to assure safety and effectiveness.

For the purposes of this guidance document, FDA considers an ''accessory'' as a medical device that is intended to support, supplement, and/or augment the performance of one or more medical devices. In practice, the distinctions among devices that support, supplement, and/or augment parent devices are subtle and many devices that we would consider to be an accessory may do more than one of these things. Thus, if the device is intended to support, supplement, and/or augment the performance of one or more parent devices, we intend to consider the device as an accessory.

Once a specific article has been determined to be an accessory, the guidance document describes how the accessory is classified based on its risks when used as intended with the intended parent device(s). In practice, FDA may classify individual accessories either by inclusion in the classification regulation of the parent device (either via a premarket submission or via express inclusion in the language of the regulation or order) or via development of a unique, separate classification regulation or order for the accessory.

For accessories of a new type, the guidance outlines the use of the *de novo* process for classification. 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 are no legally marketed predicate device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the regulation of medical device accessories. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1770 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accessory Classification De Novo Request—(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 FD&C Act to request risk-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).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number 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 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.

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.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: January 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00856 Filed 1–16–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2153]

Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes.'' FDA has received reports of blood and stool traveling through colonoscope irrigation channels and into the water bottle and tubing when the irrigation channel did not have a backflow-prevention mechanism in place. This draft guidance document, when finalized, will highlight the cross-contamination risk associated with