

regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

The Committee shall consist of a core of 21 voting members including a Chair and Co-Chair. The members, Chair, and Co-Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based-products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Committee may also include technically qualified Federal members. The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when:

(1) Expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum

requirements. If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm115356.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1771]

#### **Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions." This draft guidance provides recommendations for information and testing that should be included in 510(k) submissions for metal expandable biliary stents and their associated delivery systems intended to provide luminal patency of malignant strictures in the biliary tree. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by September 17, 2018 to ensure that the Agency considers your comment on

this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-D-1771 for "Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 "Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions" 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.

**FOR FURTHER INFORMATION CONTACT:** April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993-0002, 240-402-6510.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance provides draft recommendations for 510(k) submissions for metal expandable biliary stents and their associated delivery systems. These devices are intended to provide luminal patency of malignant strictures in the biliary tree. FDA is updating this guidance to reflect current review practices. The scope of this guidance is limited to metal expandable biliary stents regulated under 21 CFR 876.5010 (*Biliary catheter and accessories*) and with product code FGE (Catheter, Biliary, Diagnostic). This draft guidance applies only to biliary stents indicated for palliation of malignant strictures in the biliary tree. It does not apply to biliary stents indicated to treat benign strictures or stents intended to be used in the vasculature, tracheal/bronchial tubes, or other gastrointestinal anatomy. This draft guidance, when final, will supersede the guidance "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents," issued on February 5, 1998.

##### **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 current thinking of FDA on "Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### **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 Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This draft guidance is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document

number 1500070 to identify the guidance you are requesting.

#### **IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). 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 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

Dated: July 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Office of the Secretary**

##### **Office of the Assistant Secretary for Preparedness and Response; Statement of Organization, Functions and Delegations of Authority**

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 79 FR 70.535 (Nov. 26, 2014), 78 FR 25277 (April 30, 2013), 78 FR 7784 (Feb. 4, 2013), 75 FR 35.035 (June 21, 2010) to realign the functions of ASPR to reflect the changes mandated by the 21st Century Cures Act and to address ever-increasing manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and