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 Submit written requests for a single hard copy of the draft guidance document entitled ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions'' to the Office of the Center Director, Guidance and Policy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* 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.

[FR Doc. 2018–15294 Filed 7–17–18; 8:45 am]

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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

national security. The changes are as follows.

I. Under AN.10 Organization, delete all of the components and replace with the following:

A. Immediate Office of the Assistant Secretary for Preparedness and Response (ANA)
B. Office of Biomedical Advanced Research and Development Authority (ANB)
C. Office of the Principal Deputy Assistant Secretary (ANC)
D. Office of the Deputy Assistant Secretary Incident Command and Control (ANG)

II. Delete AN.20 Functions, in its entirety and replace with the following:

Section AR.20 Functions.

A. Immediate Office of the Assistant Secretary for Preparedness and Response: The Immediate Office of the Assistant Secretary for Preparedness and Response (IO/ASPR) is headed by the Assistant Secretary, who provides leadership and executive and strategic direction for the ASPR organization. The Assistant Secretary is the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. The Assistant Secretary is responsible for carrying out ASPR's mission and implementing the functions of ASPR. The IO/ASPR (1) ensures development and maintenance of liaison relationships with HHS operating and staff divisions and represents HHS at interagency meetings, as required; (2) establishes and maintains effective communications and outreach guidance and support for all external communications, including legislative and executive branch questions and inquiries, and serves as the principal advisor to the ASPR on all legislative strategies to fulfill the Office of the ASPR and the HHS mission under section 2811 and other relevant sections of the Public Health Service Act, as amended; (3) oversees advanced research, development and procurement of qualified countermeasures, security countermeasures and qualified pandemic or epidemic products; (4) coordinate with relevant federal officials to ensure integration of federal preparedness and response activities for public health emergencies; (5) manages correspondence control for the Assistant Secretary; and (6) coordinates the strategic and operational activities for public health preparedness response and recovery.

B. Office of Biomedical Advance Research and Development Authority (ANB). The Office of Biomedical Advanced Research and Development Authority (BARDA), established in April 2007 in response to the Pandemic and All-Hazards Preparedness Act of 2006, serves preparedness and response roles to provide medical countermeasures (MCM) in order to mitigate the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats and agents and emerging infectious diseases, including pandemic influenza. BARDA executes this mission by facilitating research, development, innovation, and acquisition of MCM and expanding domestic manufacturing infrastructure and surge capacity of these MCM.

BARDA is headed by a Deputy Assistant Secretary, and includes the following components:

- Division of Influenza (ANB1)
- Division of Emerging Infectious Diseases (ANB2)
- Division of Chemical, Biological, Radiological and Nuclear Threats (ANB3)
- Division of Strategic Science and Technology (ANB4)
- Division of Regulatory and Quality Affairs (ANB5)
- Division of Research, Innovation and Ventures (ANB6)

C. Office of the Principal Deputy Assistant Secretary (ANC). The Office of the Principal Deputy Assistant Secretary (OPDAS) is responsible for providing a well-integrated infrastructure that supports the Department's capabilities to prevent, prepare for, respond to and recover from natural public health and medical threats and emergencies. OPDAS leads the preparedness and response activities required to coordinate public health and healthcare response systems and activities with relevant federal, state, tribal, territorial, local, and international communities under the National Response Framework and Emergency Support Annexes #8, #6 and #14. OPDAS is responsible for the execution of business management operations and managing coordination. OPDAS provides for the facility, logistics, information technology and infrastructure support services necessary to maintain day-to-day operations of ASPR, including functions of Human Resources, Organization and Employee Development, Ethics, United States Public Health Service (USPHS) liaison, acquisitions management, contracts, grants, and all financial planning and analysis.

The Office of the Principal Deputy Assistant Secretary is headed by the Principal Deputy Assistant Secretary, and includes the following components:

- Division of Management Finance and Human Capital (ANC1)
- Division of Emergency Management and Medical Operations (ANC2)
- Division of Resource Management (ANC3)

D. Deputy Assistant Secretary Incident Command and Control (ANG): The Deputy Assistant Secretary (DAS/ICC) is responsible for the policy development, planning analysis, requirements and strategic planning. DAS/ICC manages and operates the HHS Secretary's Operation Center (SOC), intelligence, security, information management and is also responsible for the HHS Continuity of Operations (COOP) and the development of the ASPR COOP Plan. The Office of the Assistant Secretary Incident Command and Control (DAS/ICC) is headed by the Deputy Assistant Secretary Incident Command and Control, and includes the following components:

- Division of Security Intelligence and Information Management
- Division of Strategy, Policy, Planning and Requirements

III. Delegations of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Alex M. Azar II,

Secretary.

[FR Doc. 2018–15310 Filed 7–17–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.