

presentations and comments for 508 compliance, and place compliant materials on its Web site. As resources permit, CMS will also convert non-compliant submissions to 508 compliant forms, and offer assistance to submitters who wish to make their submissions 508 compliant. All non-508 compliant presentations and comments will be shared with the public onsite and through the webcast and made available to the public upon request.

Those wishing to access such materials should contact the DFO (the DFO's address, email and phone number are provided below).

In order to consider presentations and/or comments, we will need to receive the following:

1. An *email copy* of the presentation or comments sent to the DFO mailbox, APCPanel@cms.hhs.gov or, if unable to submit by email, a hard copy sent to the DFO at the address noted under **FOR FURTHER INFORMATION CONTACT**.

2. Form *CMS-20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and commenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation. Presenters and commenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's/commenter's relationship with the organization that they represent must also be clearly listed.

- The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>.

- We encourage presenters to make efforts to ensure that their presentations and comments are 508 compliant.

V. Oral Comments

In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

VI. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal

property, must register by following the instructions in the "Meeting Registration Timeframe" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

VII. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- Foreign nationals visiting any CMS facility require prior approval. If you are a foreign national and wish to attend the meeting onsite, in addition to registering for the meeting, you must also send a separate email to APCPanel@cms.hhs.gov prior to the close of registration to request authorization to attend as a foreign national.

VIII. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

IX. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations

will be posted to the CMS Web site after the meeting.

X. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016-11949 Filed 5-19-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2015.

ADDRESSES: Copies are available at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. You also may access the docket at <http://www.regulations.gov> for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2015. Insert the docket number found in brackets in the heading of this document at <http://www.regulations.gov> into the "Search" box, clear filter under Document Type (left side of screen), and check "Supporting and Related Material," then Sort By Best Match (from the drop-down menu; top right side of screen), "ID Number (Z-A)" or Sort By Best Match (from the drop-down menu) "Title (A-Z)," also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Director and Committee Management Officer,

Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, 301-796-8220.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2014 through September 30, 2015:

Center for Biologics Evaluation and Research

Blood Products Advisory Committee
National Center for Toxicological Research

Science Board to the National Center for Toxicological Research
Center for Drug Evaluation and Research

Bone, Reproductive Health Drugs Advisory Committee
Joint Meetings of the Anesthetic and Analgesic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday.

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., Rm. 133, Washington, DC; and

2. The Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2015-M-4948, FDA-2015-M-4949, FDA-2015-M-4950, FDA-2016-M-0120, FDA-2016-M-0121, FDA-2016-M-0122, FDA-2016-M-0123, FDA-2016-M-0803, FDA-2016-M-0804, FDA-2016-M-0805, FDA-2016-M-0806, FDA-2016-M-0807, FDA-2016-M-0926, FDA-2016-M-0928]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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 Nos. FDA-2015-M-4948, FDA-2015-M-4949, FDA-2015-M-4950, FDA-2016-M-0120, FDA-2016-M-0121, FDA-2016-M-0122, FDA-2016-M-0123, FDA-

2016-M-0803, FDA-2016-M-0804, FDA-2016-M-0805, FDA-2016-M-0806, FDA-2016-M-0807, FDA-2016-M-0926, FDA-2016-M-0928 for "Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire