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.

[FR Doc. 2016–11853 Filed 5–19–16; 8:45 am]

BILLING CODE 4164–01–P

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

Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2016, through March 31, 2016. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2016, THROUGH MARCH 31, 2016

PMA No., Docket No.	Applicant	Trade name	Approval date
H130006, FDA–2015–M–4950	Torax Medical, Inc	FENIX Continence Restoration System	12/18/2015
H140005, FDA–2015–M–4948	ARUP Laboratories	PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD).	12/18/2015
H140006, FDA–2015–M–4949	ARUP Laboratories	KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM).	12/18/2015
P130007/S004, FDA–2016–M–0120.	Animas Corp	Animas Vibe System	12/24/2015
P900033/S042, FDA–2016–M–0121.	Integra LifeSciences Corp	Integra Omnigraft Dermal Regeneration Matrix and Integra Dermal Regeneration Template.	1/7/2016
P080028, FDA–2016–M–0122	Storz Medical Ag	Storz Medical Duolith SD1 Shock Wave Therapy	1/8/2016
P150011, FDA–2016–M–0123	LivaNova Canada Corp	Perceval Sutureless Heart Valve	1/8/2016
P150027, FDA–2016–M–0803	Dako North America, Inc	PD–L1 IHC 28–8 pharmDx	1/23/2016
P150004, FDA–2016–M–0804	Spinal Modulation, Inc	Axium Neurostimulator System	2/11/2016
P150022, FDA–2016–M–0805	Rex Medical, L.P	Closer Vascular Sealing System	2/12/2016
P120018, FDA–2016–M–0806	Sharps Terminator, LLC	Sharps Terminator	2/17/2016
P150005, FDA–2016–M–0807	Boston Scientific Corp	Blazer Open-Irrigated Ablation Catheter System	2/24/2016
P130009/S037, FDA–2016–M–0926.	Edwards Lifesciences, LLC	SAPIEN XT Transcatheter Heart Valve and Accessories	2/29/2016
P020004/S123, FDA–2016–M–0928.	W.L. Gore & Associates, Inc	GORE EXCLUDER Iliac Branch Endoprosthesis	2/29/2016

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: May 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11856 Filed 5–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0133]

Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment.'' This guidance is intended to assist sponsors in designing a clinical development program for new drug products for the treatment of chronic obstructive pulmonary disease (COPD). This guidance revises the draft guidance of the same name, issued November 9, 2007, by adding information regarding the St. George's Respiratory Questionnaire (SGRQ).

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 on 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 July 19, 2016.

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.*