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.*

• 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 No. FDA–2007–D–0133 for ''Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability.'' 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Badrul A. Chowdhury, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 COPD. The emphasis of this guidance is on the assessment of efficacy of a new molecular entity (NME) in phase 3 clinical studies of COPD. Development of NMEs for COPD poses challenges and opportunities. Not all drugs developed for COPD will fit into the types described, and the efficacy endpoints discussed in this guidance may not fit the need for all drugs. FDA encourages sponsors to develop clinical programs that fit their particular needs and to discuss their planned approach with the Center for Drug Evaluation and Research's Division of Pulmonary, Allergy, and Rheumatology Products. For novel approaches, where warranted, outside expertise can be sought, including consultation with the Pulmonary-Allergy Drugs Advisory Committee.

This guidance revises the draft guidance of the same name, issued November 9, 2007 (72 FR 63618), by adding information on the use of SGRQ in COPD studies. FDA acknowledges the importance of assessing patient perspectives in clinical trials and therefore is interested in eliciting comment on the SGRQ, included in Appendix A.

Also, this guidance outlines FDA's thinking based on information that was available in 2007 on the development of various types of drugs for COPD. FDA acknowledges that the landscape of clinical trials has evolved since 2007 and therefore is encouraging public comment on the body of the guidance in addition to public comment on the SGRQ information added in Appendix A.

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 the development of drug products for the treatment of COPD. 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.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11855 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–2016–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.