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.

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/MedicalDevices/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Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment.”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 This guidance revises the draft guidance of the same name, issued November 9, 2007, by adding information regarding the St. George’s Respiratory Questionnaire (SGRQ).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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 19, 2016.

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

<table>
<thead>
<tr>
<th>PMA No., Docket No.</th>
<th>Applicant</th>
<th>Trade name</th>
<th>Approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>H140005, FDA–2015–M–4948</td>
<td>ARUP Laboratories</td>
<td>PDGFRA FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)</td>
<td>12/18/2015</td>
</tr>
<tr>
<td>P900003/S042, FDA–2016–M–0121</td>
<td>Integra LifeSciences Corp</td>
<td>Integra Dermal Regeneration Matrix and Integra Omnipatch Dermal Regeneration Template</td>
<td>1/7/2016</td>
</tr>
<tr>
<td>P080028, FDA–2016–M–0122</td>
<td>Storz Medical AG</td>
<td>Percival Sutureless Heart Valve</td>
<td>1/8/2016</td>
</tr>
<tr>
<td>P020004/S123, FDA–2016–M–0928</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ADDRESS: 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.
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 comments on the SGRQ information added 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.

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