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


For further information contact:
Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, 301–796–8220.

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.”


For further information contact:
Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, 301–796–8220.

For Further Information Contact:
Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, 301–796–8220.

For Further Information Contact:
Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, 301–796–8220.
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 business information, 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.

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.電子アクセス

インターネットにアクセスを持つ人々は、http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htmで、この文書を閲覧できます。

日付: 2016年5月16日
レスリー・クックス
政策委員会委員長

[FR Doc. 2016–11856 診 5–19–16; 8:45 am]
BILLING CODE 4164–01–P

健康と人間サービス省

食薬局

[Docket No. FDA–2007–D–0133]

慢性閉塞性肺疾患: 新薬開発のための治療; 意見提示ガイドライン:業界への用意

機関: 食薬局, HHS.

行動: 意見提示の通知

概要: 食薬局（FDAまたは業界）は、新薬開発のための治療のためのガイドラインの用意を公表します。このガイドラインは、新しい薬品の開発プログラムの設計を手助けするために作成されました。このガイドラインは、慢性的閉塞性肺疾患（COPD）の薬を手助けするための新しい薬品の開発プログラムを設計するために作成されました。このガイドラインは、同名のガイドラインの改訂版です。2007年11月9日に、St. George’s Respiration Questionnaire（SGRQ）の情報による改善が加えられました。

期間: 考えている場合、この最終版のガイドラインに進める前に、その開発プログラムの設計を手助けするための新しい薬品の開発プログラムを手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。この場合、開発プログラムの設計を手助けするために、この農業体がその意見を公表することを決定します。