Dated: February 9, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–02976 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on April 12, 2016, from 8:30 a.m. to 1 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

Questions about accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–706–9001, FAX: 301–847–8533, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 208542, rociletinib tablets, application submitted by Clovis Oncology, Inc. The proposed indication (use) for this product is for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 29, 2016. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 21, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 22, 2016. Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Lauren D. Tosh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 8, 2016.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–03011 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0412]

Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax; 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 “Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax.” The purpose of this draft guidance is to assist sponsors in the development of new drugs for the prophylaxis of inhalational anthrax. This draft guidance supersedes the draft guidance entitled “Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs” issued in March 2002.

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 April 18, 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

• 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–
2016–D–0412 for “Anthrax: Developing
Drugs for Prophylaxis of Inhalational
Anthrax; 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 docket, 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT:
Joseph G. Toerner, Center for Drug
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 22, Rm. 6244,
Silver Spring, MD 20993–0002, 301–
796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a
draft guidance for industry entitled
“Anthrax: Developing Drugs for
Prophylaxis of Inhalational Anthrax.”
The purpose of this draft guidance is to
assist sponsors in the development of
new drugs to be administered to persons
who have inhaled Bacillus anthracis
spores. Drugs have not yet manifested
clinical evidence of disease, to prevent
the development of inhalational anthrax
disease. We refer to this indication as
“prophylaxis of inhalational anthrax.”
This draft guidance describes
approaches for the designs of the animal
model efficacy studies and recognizes
that drug development for the sole
indication of prophylaxis of inhalational
anthrax is possible.

This draft guidance supersedes the
draft guidance for industry entitled
“Inhalational Anthrax (Post-Exposure)—
Developing Antimicrobial Drugs”
published in March 2002 (2002 draft
guidance). The 2002 draft guidance
stated that drugs for the prophylaxis of
inhalational anthrax would be approved
under the accelerated approval
regulations (21 CFR part 314, subpart H,
for drugs and 21 CFR part 601, subpart E,
for biological products), unless the
drug already carried an anthrax
indication. Shortly after the 2002 draft
guidance issued, FDA amended its
regulations to provide a regulatory
mechanism to approve drugs and
biological products when human
efficacy studies are not ethical or
feasible (part 314, subpart I, for drugs
and part 601, subpart H, for biological
products). These regulations are
commonly referred to as the “animal
rule.”

This draft guidance states that
drugs developed for prophylaxis of
inhalational anthrax will be considered
for approval under the animal rule
regulations. Other changes from the
2002 draft guidance are incorporated
into the appropriate sections of this
guidance and are based on comments
received to the docket for the 2002 draft
guidance as well as recent
developments in scientific information
that pertain to drugs being developed
for prophylaxis of inhalational anthrax.
Issuance of this draft guidance fulfills
a portion of the requirements of Title
VIII, section 804, of the Food and Drug
Administration Safety and Innovation
Act (Pub. L. 112–144), which requires
FDA to review and, as appropriate,
revise not fewer than three guidance
documents per year for the conduct of
clinical trials with respect to
antibacterial and antifungal drugs.

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 this topic. It does not establish any
rights for any person and is not binding

1 The animal rule regulations in this guidance
specifically refer to part 314, subpart I, for drugs
and part 601, subpart H, for biological products. In
October 2015, FDA finalized the guidance for
industry entitled “Product Development Under the
Animal Rule” that contains general information and
recommendations on the development and approval
of products under the animal rule.
on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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: February 9, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–02964 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2012–D–1010]

Completeness Assessments for Type II Active Pharmaceutical Ingredient Drug Master Files Under the Generic Drug User Fee Amendments of 2012; 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 guidance for industry entitled “Completeness Assessments for Type II API DMFs Under GDUFA”. It finalizes the draft guidance entitled “Initial Completeness Assessments for Type II API DMFs Under GDUFA”, which published on October 2, 2012. This guidance is intended for holders of Type II active pharmaceutical ingredient (API) drug master files (DMFs) that are or will be referenced in an abbreviated new drug application (ANDA), an amendment to an ANDA, a prior approval supplement (PAS) to an ANDA, or an amendment to a PAS (generic drug submissions).

DATES: Submit either electronic or written comments on Agency guidances at any time.

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 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–2012–D–1010 for “Completeness Assessments for Type II API DMFs Under GDUFA”. 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 publically 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 docket, 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 this 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New