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: January 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–01165 Filed 1–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0002]

Conditional Approval of a New Animal Drug No Longer In Effect; Masitinib Mesylate Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conditional approval no longer in effect.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that the conditional approval of an application for masitinib mesylate tablets, a new animal drug for a minor use, is no longer in effect.

DATES: Conditional approval is no longer in effect as of December 15, 2015.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann III, Center for Veterinary Medicine (HFV–108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0652, *herman.schoenemann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282), permits conditional approval of new animal drugs for minor uses. Conditional approval of a new animal drug is effective for a 1-year period, and may be renewed for up to four additional 1-year periods. The holder of a conditionally approved new animal drug is required to submit all information necessary to support a complete new animal drug application (NADA) under section 512(b)(1) of the FD&C Act (21 U.S.C. 360b(b)(1) by 180 days before the termination of the fifth 1-year period of conditional approval. If FDA does not approve an NADA for the new animal drug by the termination date of the conditional approval, then pursuant to section 571(h) of the FD&C Act (21 U.S.C. 360ccc(h)) the conditional approval is no longer in effect.

AB Science, 3 Avenue George V, 75008 Paris, France, filed an application for conditional approval (141–308) that provided for veterinary prescription use of KINAVET–CA1 (masitinib mesylate) Tablets for the treatment of recurrent (post-surgery) or nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids. That application was conditionally approved on December 15, 2010.

On December 15, 2014, application 141–308 received the fourth and final renewal of its conditional approval. That final renewal terminated on December 15, 2015. As of that date, FDA did not approve an NADA for KINAVET–CA1 under section 512 of the FD&C Act. Consequently, as of December 15, 2015, the conditional approval of application 141–308 is no longer in effect.

Because the conditional approval is no longer in effect, KINAVET–CA1 Tablets is now an unapproved new animal drug product with no legal marketing status. Further marketing, sales, and distribution of the product are illegal.

This notice is issued under section 571 of the FD&C Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine.

Elsewhere in this issue of the **Federal Register,** FDA is amending the animal drug regulations to reflect that the conditional approval of an application for this new animal drug is no longer in effect.

Dated: January 14, 2016.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2016–01104 Filed 1–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0749]

Implanted Blood Access Devices for Hemodialysis; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Implanted Blood Access Devices for Hemodialysis.'' This guidance was developed to support the reclassification of the implanted blood access devices for hemodialysis into class II (special controls) and to assist industry in preparing premarket notification (510(k)) submissions for implanted blood access devices for hemodialysis.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome 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 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–

2013–D–0749 for ''Implanted Blood Access Devices for Hemodialysis.'' 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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Implanted Blood Access Devices for Hemodialysis'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations to assist manufacturers in developing their premarket submissions of implanted blood access devices for hemodialysis regulated under 21 CFR 876.5540(a)(1). The draft of this guidance document was issued concurrently with the proposed reclassification of implanted blood access devices under § 876.5540(a)(1). FDA published a proposed order to reclassify this device in the **Federal Register** of June 28, 2013 (78 FR 38867) and announced the availability of the draft guidance elsewhere in the same issue of the **Federal Register** (78 FR 38994). The comment period for the draft guidance closed on August 27, 2013. FDA also held a meeting of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (the Panel), on June 27, 2013 (78 FR 25747, May 2, 2013), to discuss whether implanted blood access devices should be reclassified or remain in class III. The draft guidance supported the proposed reclassification.

In response to the draft guidance, FDA received comments from one commenter. The comments, in addition to the feedback from the Panel, were considered and discussed in the final order reclassifying this device type into class II (special controls) (79 FR 43241, July 25, 2014). This final guidance references the special controls for this device type, and the recommendations in the draft guidance were modified to be consistent with revisions to the special controls as codified in the final order.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on implanted blood access devices for hemodialysis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Implanted Blood Access Devices for Hemodialysis'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1781 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 50 and 56 have been approved under OMB control number 0910–0130.

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01094 Filed 1–20–16; 8:45 am]

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