*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### Conditional Approval of a New Animal Drug No Longer In Effect; Masitinib Mesylate Tablets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**ACTION:** Notice of conditional approval no longer in effect.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that the conditional approval of an application for masitinib mesylate tablets, a new animal drug for a minor use, is no longer in effect.

**DATES:** Conditional approval is no longer in effect as of December 15, 2015.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conditional approval, then pursuant to section 571(h) of the FD&C Act (21 U.S.C. 360ccc(h)) the conditional approval is no longer in effect.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–