

Application No.	Drug	Applicant
ANDA 062436	T-STAT (erythromycin) Solution; Topical, 2%	Westwood-Squibb Pharmaceuticals, Inc.
ANDA 080439	CHLORPROMAZINE HCl (chlorpromazine HCl) Tablet; Oral, 10 mg; 25 mg; 50 mg; 100 mg; 200 mg.	Sandoz Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01097 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-2016-N-0001]

Cellular, Tissue and Gene Therapies 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies 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 February 16, 2016 from 1 p.m. to 5 p.m.

Location: FDA White Oak Conference Center, rm 1503. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Janie Kim or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-9016 or 240-402-8072, janie.kim@fda.hhs.gov or Rosanna.Harvey@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: On February 16, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Tumor Vaccines and Biotechnology Branch and the Cellular and Tissue Therapy Branch of the Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapy, Center for Biologics Evaluation and Research, FDA.

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: On February 16, 2016, from 1:00 p.m. to 3:55 p.m., the meeting is open to the public. 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 February 1, 2016. Oral presentations from the public will be scheduled between approximately 2:55 p.m. to 3:55 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 January 22, 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 January 25, 2016.

Closed Committee Deliberations: On February 16, 2016, from 3:55 p.m. to 5:00 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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 accommodations due to a disability, please contact Janie Kim 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: 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-