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Conditional Approval of a New Animal Drug No Longer In Effect; Masitinib Mesylate Tablets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ACTION: Notice of conditional approval no longer in effect.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that the conditional approval of an application for masitinib mesylate tablets, a new animal drug for a minor use, is no longer in effect.

DATES: Conditional approval is no longer in effect as of December 15, 2015.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, 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 Consequently, as of December 15, 2015, the conditional approval of application 141–308 is no longer in effect.

Because the conditional approval is no longer in effect, KINAVET–CA1 Tablets is now an unapproved new animal drug product with no legal marketing status.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 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to reclassify this device in the Federal Register of June 28, 2013 (78 FR 38867) and announced the availability of the draft guidance elsewhere in the same issue of the Federal Register (78 FR 38994). The comment period for the draft guidance closed on August 27, 2013.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 821 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR parts 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]

BILLING CODE 4164–01–P