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Conditional Approval of a New Animal Drug No Longer In Effect; Masitinib Mesylate Tablets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ACTION: Notice of conditional approval no longer in effect.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that the conditional approval of an application for masitinib mesylate tablets, a new animal drug for a minor use, is no longer in effect.

DATES: Conditional approval is no longer in effect as of December 15, 2015.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approval, then pursuant to section 571(h) of the FD&C Act (21 U.S.C. 360ccc(h)) the conditional approval is no longer in effect.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

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