4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA-2012-N-0002]

Conditionally Approved New Animal Drugs for Minor Use and Minor Species; Masitinib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a conditionally approved supplemental application for conditional approval of a new animal drug (CNADA) intended for a minor use filed by AB Science. The supplemental CNADA provides for a revised indication for masitinib mesylate tablets in dogs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Steven Fleischer,

Center for Veterinary Medicine (HFV-110),

Food and Drug Administration,

7500 Standish Pl.,

Rockville, MD 20855,

240-276-8234,

email: steven.fleischer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: AB Science, 3 Avenue George V, 75008 Paris, France,

filed a supplemental CNADA 141-308 for KINAVET-CA1 (masitinib mesylate) Tablets for a revised indication for the treatment of nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids. In accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), this supplemental application is conditionally approved as of January 30, 2012, and the regulations in 21 CFR part 516 are amended to reflect this action.

A summary of safety and effectiveness data and information submitted to support conditional approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

KINAVET-CA1 (masitinib mesylate) Tablets for the intended uses conditionally approved by FDA under application number 141-308 qualifies for 7 years of exclusive marketing rights beginning on December 15, 2010, the date of the original conditional approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the FD&C Act (21 U.S.C. 360ccc-2(c)) because it has been declared a designated new animal drug by FDA under section 573(a) of the FD&C Act.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 516 is amended as follows:

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

2. In § 516.1318, revise paragraph (c)(2) to read as follows:

§ 516.1318 Masitinib.

* * * * *

(c) * * *

(2) Indications for use. For the treatment of nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

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Dated: June 8, 2012.

Signed: Elizabeth Rettie,

Deputy Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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