



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 516

[Docket No. FDA-2015-N-0002]

Conditional Approval of a New Animal Drug No Longer In Effect; Masitinib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 that the conditional approval of an application for masitinib mesylate tablets, a new animal drug for a minor use, is no longer in effect.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: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect that application 141-308 for conditional approval of KINAVET-CA1 (masitinib mesylate) Tablets, a new animal drug for a minor use sponsored by AB Science, 3 Avenue George V, 75008 Paris, France, is no longer in effect.

Elsewhere in this issue of the Federal Register, FDA gave notice that conditional approval of this drug, by operation of law, was no longer in effect as of December 15, 2015.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 516 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "AB Science" and in the table in paragraph (c)(2), remove the entry for "052913".

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

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

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

§ 516.1318 [Removed]

4. Remove § 516.1318.

Dated: January 14, 2016.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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