4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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

Oral Dosage Form New Animal Drugs; Change of Sponsor; Griseofulvin Powder; Levamisole Hydrochloride Powder; Oxytetracycline Powder

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 change of sponsor for five abbreviated new animal drug applications (ANADAs) for griseofulvin powder, levamisole hydrochloride soluble powder, and oxytetracycline hydrochloride soluble powder from Teva Animal Health, Inc., to Cross Vetpharm Group, Ltd.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-391 for Griseofulvin Powder, ANADAs 200-146 and 200-247 for Oxytetracycline Hydrochloride Soluble Powder, and ANADAs 200-313 and 200-386 for Levamisole Hydrochloride Soluble Pig Wormer and Drench Powder to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. Accordingly, the agency is amending the regulations in part 520 (21 CFR part 520) to reflect the transfer of ownership and a current format.

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 520

Animal drugs.

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 part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1100 [Amended]

2. In paragraph (b)(2) of § 520.1100, remove "059130" and in its place add "061623".

3. In § 520.1242, revise the section heading to read as follows:

§ 520.1242 Levamisole.

4. In § 520.1242a, revise the section heading to read as set forth below, and in paragraph (b)(4) remove “059130” and in its place add “061623”.

§ 520.1242a Levamisole powder.

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§ 520.1660d [Amended]

5. In § 520.1660d, in paragraphs (b)(5), (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove "059130" and in its place add "061623".

Dated: May 7, 2012.

Signed: Elizabeth Rettie,

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

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