DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

New Animal Drugs; Change of Sponsor

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 two approved new animal drug applications (NADAs) and an approved abbreviated new animal drug application (ANADA) from Lambert-Kay, A Division of Carter-Wallace, Inc., to Church & Dwight Co., Inc. The drug labeler code for Church & Dwight Co., Inc., is also being listed.

DATES: This rule is effective [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512–0181, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 101–497 for TINY TIGER (dichlorophene/toluene) Worming Capsules, NADA 101–498 for LK (dichlorophene/toluene) Worming Capsules, and ANADA 200–028 for EVICT (pyrantel pamoate) Liquid Wormer to Church & Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543–5297. Accordingly, the agency is amending the regulations in §§ 520.580 and 520.2043 (21 CFR 520.580 and 520.2043) to reflect the transfer of ownership.
Church & Dwight Co., Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. Following these changes of sponsorship, Lambert-Kay is no longer the sponsor of any approved applications. Accordingly, 21 CFR 510.600(c)(1) and (c)(2) is being amended to add entries for Church & Dwight Co., Inc., and to remove the entries for Lambert-Kay. Also, § 520.2043 is being revised to reflect 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

21 CFR Part 510

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

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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


2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Lambert-Kay, A Division of Carter-Wallace, Inc." and by alphabetically adding an entry for "Church & Dwight Co., Inc." and in the table in paragraph (c)(2) by removing the entry "011615" and by numerically adding an entry for "010237" to read as follows:
§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(c) * * *

(1) * * *

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
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<tr>
<td>Church &amp; Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543–5297</td>
<td>010237</td>
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(2) * * *

<table>
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<tr>
<td>010237</td>
<td>Church &amp; Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543–5297</td>
</tr>
</tbody>
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PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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


§ 520.580 [Amended]

4. Section 520.580 Dichlorophene and toluene capsules is amended by removing footnote 1 every place it appears in the section and in paragraph (b)(1) by removing “011615” and by adding in its place “010237”.

5. Section 520.2043 is revised to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

(a) Specifications. (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.
(b) Sponsors. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 000069 and 059130 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 000069, 010237, and 059130 for use of the products described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) Special considerations. See § 500.25 of this chapter.

(d) Conditions of use—(1) Horses and ponies. It is used as follows:

(i) Amount. 3 mg per pound (/lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) Indications for use. For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus vulgaris, S. edentatus, S. equinus), small strongyles, pinworms (Oxyuris), and large roundworms (Parascaris).

(iii) Limitations. Not for use in horses and ponies to be slaughtered for food purposes. When the drug is for administration by stomach tube, it shall be labeled: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(2) Dogs. It is used as follows:

(i) Dogs and puppies—(A) Amount. 2.27 mg/lb body weight as a single dose in the animal’s feed bowl by itself or mixed in a small quantity of food.

(B) Indications for use. For the removal of large roundworms (Toxocara canis and Toxascaras leonina) and hookworms (Ancylostoma caninum and Uncinaria stenocephala).

(C) Limitations. Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) Dogs, puppies, and lactating bitches after whelping—(A) Amount. 2.27 mg/lb body weight.

(B) Indications for use. To prevent reinfections of T. canis.
(C) Limitations. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

Dated: 5/24/02
May 24, 2002.

Andrew J. Beaulieu,
Acting Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 02–???? Filed ??–??–02; 8:45 am]

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Dawn F. Hartline