DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 524

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 12 approved new animal drug applications (NADAs) from A. H. Robins Co. to Fort Dodge Animal Health, Division of Wyeth.

DATES: This rule is effective November 6, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501–0518, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 12 approved NADAs to Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501:

NADA Number	Product Name
034–879	DOPRAM–V Injectable
038–838	ROBAXIN–V Injectable
045–715	ROBAXIN–V Tablets
091–065	ROBIZONE–V
093–105	ROBIZONE–V
098–640	ROBIZONE Injectable 20%
101–777	Robinul-V Injectable
106–111	Telazol
136–651	Guailaxin
141–003	Derm-Otic Ointment
141–004	Robamox-V
141–005	Robamox-V Tablets

Accordingly, the agency is amending the regulations in 21 CFR 520.88b, 520.88f, 520.1380, 520.1720a, 522.775, 522.1066, 522.1085, 522.1380, 522.1720, 522.2470, and 524.1600a to reflect the transfer of ownership and to reflect current format.

Following this change of sponsorship, A. H. Robins Co. is no longer the sponsor of any approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for A. H. Robins Co.

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 Parts 520, 522, and 524

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, 520, 522, and 524 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. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''A. H. Robins Co.'' and in the table in paragraph (c)(2) by removing the entry for ''000031''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.88b [Amended]

4. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing ''000031 and 000093'' and by adding in its place ''000093 and 000856''.

§ 520.88f [Amended]

5. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing ''000031 or 000093'' and by adding in its place ''000093 and 000856''.

§ 520.1380 [Amended]

6. Section 520.1380 *Methocarbamol tablets* is amended in paragraph (c) by removing ''000031'' and by adding in its place ''000856''.

§ 520.1720a [Amended]

7. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing ''000031''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

8. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.775 [Amended]

9. Section 522.775 *Doxapram hydrochloride injection* is amended in paragraph (b) by removing ''000031'' and by adding in its place ''000856''.

§ 522.1066 [Amended]

10. Section 522.1066 *Glycopyrrolate injection* is amended in paragraph (b) by removing ''000031'' and by adding in its place ''000856''.

§ 522.1085 [Amended]

11. Section 522.1085 *Guaifenesin sterile powder* is amended in paragraph (b) by removing ''No. 000031'' and by adding in its place ''Nos. 000856''.

§ 522.1380 [Amended]

12. Section 522.1380 *Methocarbamol injection* is amended in paragraph (b) by removing ''000031'' and by adding in its place ''No. 000856''.

§ 522.1720 [Amended]

13. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing ''000031'' and by numerically adding ''000856''.

§ 522.2470 [Amended]

14. Section 522.2470 *Tiletamine hydrochloride and zolazepam hydrochloride for injection* is amended in paragraph (b) by removing ''000031'' and by adding in its place ''000856''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

15. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1600a [Amended]

16. Section 524.1600a *Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment* is amended in paragraph (b) by removing ''000031'' and by numerically adding ''000856''.

Dated: October 28, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–28156 Filed 11–5–02; 8:45 am]

BILLING CODE 4160–01–S