DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, and 558

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 25 approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) from Bimeda, Inc., to Cross Vetpharm Group Ltd.

DATES: This rule is effective January 31, 2003.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967; e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Bimeda, Inc., 291 Forest Prairie Rd., LeSueur, MN 56058, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 25 approved NADAs and ANADAs to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

NADA Number	Trade Name
010–092	GALLIMYCIN 50
010–346	COMBUTHAL Powder
012–123	ERYTHRO–100, –200; GALLIMYCIN Injectable
035–157	GALLIMYCIN 100; GALLIMYCIN 500
035–455	ERYTHRO–36 Dry; GALLIMYCIN–36 Dry
035–456	GALLIMYCIN–36 Sterile
038–241	ERYTHRO (High Lev)/Zoalene Plus Arsanilic Acid
038–242	ERYTHRO (Low Lev)/Amp Plus Etho
038–624	PRO-GALLIMYCIN–10
038–661	SPECTAM Water Soluble Concentrate
041–955	Erythromycin Medicated Premix
044–756	TEVCODYNE
055–059	TEVCOCIN Tablets
093–515	SPECTAM Tablets
095–218	Dexamethasone Tablets, 0.25 mg
100–128	Supersweet Medipak TYLAN 10
101–690	ERYTHRO–100 Injection
107–506	CARBAM Tablets
118–032	CARBAM PALATABS
118–979	BUTATRON Gel
120–615	SUSTAIN III Bolus
126–504	Nitrofurazone Ointment
200–050	Neomycin 325 Soluble Powder
200–103	Penicillin G Potassium, USP
200–144	Oxytetracycline HCl Soluble Powder; TETROXY

Accordingly, the agency is amending the regulations in 21 CFR 520.390a, 520.540b, 520.622a, 520.823, 520.1484, 520.1660d, 520.1696b, 520.1720a, 520.1720d, 520.2123a, 520.2123b, 520.2260b, 522.820, 522.2444b, 524.1580b, 526.820, 558.248, and 558.625 to reflect the transfer of ownership.

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

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, 524, and 526

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

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, 524, 526, and 558 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 ''Bimeda, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''061133''.

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.

§ 520.390a [Amended]

4. Section 520.390a *Chloramphenicol tablets* is amended in paragraph (b)(2) by removing ''061133'' and by adding in its place ''061623''.

§ 520.540b [Amended]

5. Section 520.540b *Dexamethasone tablets and boluses* is amended in paragraph (b)(2) by removing ''061133'' and by adding in its place ''061623''.

§ 520.622a [Amended]

6. Section 520.622a *Diethylcarbamazine citrate tablets* is amended in paragraph (a)(3) by removing ''061133'' and by adding in its place ''061623''.

§ 520.823 [Amended]

7. Section 520.823 *Erythromycin phosphate* is amended in paragraphs (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.1484 [Amended]

8. Section 520.1484 *Neomycin sulfate soluble powder* is amended in paragraph (b)(2) by removing ''061133'' and by adding in its place ''061623''.

§ 520.1660d [Amended]

9. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (b)(7) by removing ''061133'' and by adding in its place ''061623''.

§ 520.1696b [Amended]

10. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.1720a [Amended]

11. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by

removing ''061133'' and by adding in its place ''061623''.

§ 520.1720d [Amended]

12. Section 520.1720d *Phenylbutazone gel* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''No. 061623''.

§ 520.2123a [Amended]

13. Section 520.2123a *Spectinomycin dihydrochloride pentahydrate tablets* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.2123b [Amended]

14. Section 520.2123b *Spectinomycin dihydrochloride pentahydrate soluble powder* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

§ 520.2260b [Amended]

15. Section 520.2260b *Sulfamethazine sustained-release boluses* is amended in paragraphs (c)(1) and (e)(1) by removing ''061133'' and by adding in its place ''061623''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.820 [Amended]

17. Section 522.820 *Erythromycin injection* is amended in paragraph (a) by removing ''061133'' and by adding in its place ''No. 061623''.

§ 522.2444b [Amended]

18. Section 522.2444b *Sodium thiopental, sodium pentobarbital for injection* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1580b [Amended]

20. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

21. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.820 [Amended]

22. Section 526.820 *Erythromycin* is amended in paragraph (b) by removing ''061133'' and by adding in its place ''061623''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

23. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.248 [Amended]

24. Section 558.248 *Erythromycin thiocyanate* is amended in paragraphs (a)(1) and (a)(2) by removing ''061133'' and by adding in its place ''061623''; and in the table in paragraph (d)(1) in the ''Sponsor'' column by removing ''061133'' wherever it appears and by adding in its place ''061623''.

§ 558.625 [Amended]

25. Section 558.625 *Tylosin* is amended in the table in paragraph (b)(39) by removing ''061133'' and by adding in its place ''061623''.

Dated: January 6, 2003.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Triamcinolone Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by RMS Laboratories, Inc. The NADA provides for use of triamcinolone topical spray in dogs for the control of pruritus associated with allergic dermatitis.

DATES: This rule is effective January 31, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474, filed NADA 141–210 that provides for use of GENESIS (triamcinolone acetonide) Topical Spray in dogs for the control of pruritus associated with allergic dermatitis. The NADA is approved as of November 4, 2002, and the regulations are amended in part 524 (21 CFR part 524) by adding new § 524.2482 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, RMS Laboratories, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 4, 2002.

The agency has determined under 21 CFR 25.33(d)(1) 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

21 CFR Part 510

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

21 CFR Part 524

Animal drugs.

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 parts 510 and 524 are amended as follows: