

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

ACTION: Final rule.

DMB

Display Date	<u>3-8-01</u>
Publication Date	<u>3-9-01</u>
Certifier	<u>FAZ</u>

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 25 approved new animal drug applications (NADA's) from Merial Ltd. to Bimeda, Inc.

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

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058-9322.

Accordingly, the agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, 526, and 558 to reflect the change of sponsor. The agency is also amending § 510.60(c)(1) and (c)(2) to add the sponsor name and drug labeler code 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.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Bimeda, Inc.” and in the table in paragraph (c)(2) by numerically adding an entry for “061133” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058-9322 *	* 061133 *

(2) * * *

Drug labeler code	Firm name and address
* 061133 *	* Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058-9322 *

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 “050604” and by adding in its place “061133”.

§ 520.540b [Amended]

5. Section 520.540b *Dexamethasone tablets and boluses* is amended in paragraph (b)(2) by removing “050604” and by adding in its place “061133”.

§ 520.622a [Amended]

6. Section 520.622a *Diethylcarbamazine citrate tablets* is amended in paragraph (a)(3) by removing “050604” and by adding in its place “061133”.

§ 520.622c [Amended]

7. Section 520.622c *Diethylcarbamazine citrate chewable tablets* is amended in paragraph (b)(4) by removing “050604” and by adding in its place “061133”.

§ 520.823 [Amended]

8. Section 522.823 *Erythromycin phosphate* is amended in paragraph (b) by removing “050604” and by adding in its place “061133”.

§ 520.1484 [Amended]

9. Section 520.1484 *Neomycin sulfate soluble powder* is amended in paragraph (b) by removing “050604, and” and adding “, and 061133” after “after 051259”.

§ 520.1660d [Amended]

10. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (b)(7) by removing “050604” and by adding in its place “061133”.

§ 520.1696b [Amended]

11. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) by removing “050604, and” and by adding in its place “add 061133” after “053501”.

§ 520.1720a [Amended]

12. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing “and 059130” and by adding in its place “059130, and 061133”.

§ 520.1720d [Amended]

13. Section 520.1720d *Phenylbutazone gel* is amended in paragraph (b) by removing “050604” and by adding in its place “061133”.

§ 520.2123a [Amended]

14. Section 520.2123a *Spectinomycin dihydrochloride pentahydrate tablets* is amended in paragraph (b), by removing “050604” and by adding in its place “061133”.

§ 520.2123b [Amended]

15. Section 520.2123b *Spectinomycin dihydrochloride pentahydrate soluble powder* is amended in paragraph (b) by removing “050604” and by adding in its place “061133”.

§ 520.2260b [Amended]

16. Section 520.2260b *Sulfamethazine sustained-release boluses* is amended in paragraphs (c)(1) and (e)(1) by removing “050604” and by adding in its place “061133”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.820 [Amended]

18. Section 522.820 *Erythromycin injection* is amended in paragraph (a) by removing “050604” and by adding its place “061133”.

§ 522.2444b [Amended]

19. Section 522.2444b *Sodium thiopental, sodium pentobarbital for injection* is amended in paragraph (b) by removing “050604” and by adding in its place “061133”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1580b [Amended]

21. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing “and 051259” and by adding in its place “051259, and 061133”.

PART 526—INTRAMAMMARY DOSAGE FORMS

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

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

§ 526.820 [Amended]

23. Section 526.820 *Erythromycin* is amended in paragraph (b) by removing “050604” and by adding in its place “061133”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.58 [Amended]

25. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1), in item (iii), for the entry “Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5”, under the “Sponsor” column by adding “061133”.

26. Section 558.62 is amended by revising paragraph (a)(1), by adding paragraph (a)(3), and in the table in paragraph (c)(1) by redesignating entries (c)(1)(iii), (c)(1)(iv), and (c)(1)(v) as entries (c)(1)(iv), (c)(1)(vi), and (c)(1)(vii), respectively, and by adding new entries (c)(1)(iii) and (c)(1)(v) to read as follows:

§ 558.62 Arsanilic acid.

(a) * * *

(1) To 015565: 20, 50, and 100 percent for use as in the table in paragraph (c)(1), entry (ii), item 1; entry (ii), item 2; entry (iv); entry (vi); and entry (vii) of this section.

* * * * *

(3) To 061133: 90 grams per pound arsanilic acid and 4.6 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (iii); 90 grams per pound arsanilic acid and 9.25 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (v).

* * * * *

(c) * * *

(1) * * *

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii)	Erythromycin 4.6	Chickens; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.	012487
(v)	Erythromycin 9.25	Chickens; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.	012487

* * * * *

§ 558.248 [Amended]

27. Section 558.248 *Erythromycin thiocyanate* is amended in paragraphs (a)(1) and (a)(2) by removing “050604” and by adding in its place “061133”, and in the table in paragraph (d)(1), in entries (i) through (vi), under the “Sponsor” column by removing “050604” wherever it appears and by adding in its place “061133”.

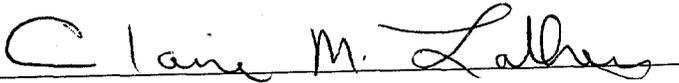
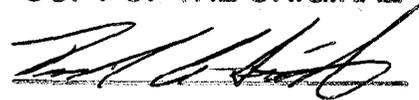
§ 558.625 [Amended]

28. Section 558.625 *Tylosin* is amended in paragraph (b)(39) by removing “50604” and by adding in its place “061133”.

Dated: _____

1/29/01
January 29, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



Claire M. Lathers,
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