

rulemaking is not required when an agency, for good cause, finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."³ The amendments to the instructions in Form 24F-2 regarding the applicable fee rate and interest rate on late fees are technical changes that simply advise investment company issuers where to find the applicable rate for calculating registration fees and the interest rate applicable to late payments (neither of which is set by the Commission). The amendments are needed now because late winter and early spring is the peak time for registration of investment company securities.⁴ Accordingly, we find that there is no need to publish notice of these amendments.⁵

The APA also requires publication of a rule at least 30 days before its effective date unless the agency finds otherwise for good cause.⁶ For the same reasons described with respect to opportunity for notice and comment, we find there is good cause for the amendments to take effect on March 12, 2001.

List of Subjects in 17 CFR Part 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Form Amendments

For the reasons set forth in the preamble, Form 24F-2, referenced in § 274.24, Title 17, Chapter II of the Code of Federal Regulations, is amended as follows:

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

1. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a-8, 80a-24, and 80a-29, unless otherwise noted.

³ 5 U.S.C. 553(b)(3)(B).

⁴ Form 24F-2 must be filed within 90 calendar days after the end of an issuer's fiscal year. 17 CFR 270.24f-2(a). Many issuers' fiscal year coincides with the calendar year. To register securities issued in fiscal year 2000, these issuers must file Form 24F-2 by April 2, 2001 (the first business day following the 90-day period, which ends March 31, 2001).

⁵ For similar reasons, the amendments do not require analysis under the Regulatory Flexibility Act or analysis of major rule status under the Small Business Regulatory Enforcement Fairness Act. See 5 U.S.C. 601(2) (for purposes of Regulatory Flexibility Act analyses, the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking); 5 U.S.C. 804(3)(C) (for purposes of Congressional review of agency rulemaking, the term "rule" does not include any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties).

⁶ See 5 U.S.C. 553(d)(3).

2. Form 24F-2 (referenced in § 274.24) is amended by revising Instruction C.9 and Instruction D.1 to read as follows:

Note: Form 24F-2 does not, and the amendments will not, appear in the *Code of Federal Regulations*.

Form 24F-2

Annual Notice of Securities Sold Pursuant to Rule 24f-2

* * * * *

Instructions

* * * * *

C. Computation of Registration Fee

* * * * *

9. Item 5(vii)—The Commission determines the rate for calculating the registration fee (the "fee rate") according to section 6(b) of the Securities Act [15 U.S.C. 77f(b)]. The registration fee is calculated by multiplying the net sales amount (Item 5(v)) by the fee rate. The fee rate is subject to change from time to time, without notice, by act of Congress through appropriations for the Commission or other laws. Issuers should determine the current fee rate before they file by referring to section 6(b) and any law or regulation affecting section 6(b). Issuers also may check the Commission's latest fee rate advisory, which is available under "Press Releases" on the "News & Public Statements" page of the Commission's Internet site at <http://www.sec.gov>. Unless otherwise specified by act of Congress, the fee rate in effect at the time of filing applies to all securities sold during the fiscal year, regardless of whether the fee rate changes during the year.

* * * * *

D. Computation of Interest Due If Form Is Filed Late

1. Item 7—Section 24(f) requires any issuer that pays its registration fee after the Due Date (see Instruction A.2) to pay interest to the Commission on fees that are not paid on time. The payment of interest does not preclude the Commission from bringing an action to enforce the requirements of section 24(f). Under section 11 of the Debt Collection Act (31 U.S.C. 3717(a)), the interest rate is published by the Secretary of the Treasury. The rate is computed annually and is effective on January 1 each year. In some circumstances the rate may be changed on a quarterly basis. Filers owing interest should verify the current interest rate. Filers can find the rate by looking for the "current value of funds rate" on the Treasury Department's Financial Management Service Internet site at <http://www.fms.treas.gov>, or by calling (202) 874-6995.

* * * * *

Dated: March 5, 2001.

By the Commission.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 01-5791 Filed 3-8-01; 8:45 am]

BILLING CODE 8010-01-U

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.

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 March 9, 2001.

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 by adding “, and 061133” 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 “, and 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 in 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: January 29, 2001

Claire M. Lathers,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 01-5680 Filed 3-8-01; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 97P-0350]

Medical Devices; Reclassification and Codification of Home Uterine Activity Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to GE Marquette Medical Systems, Inc., reclassifying from class III to class II (special controls) the Corometrics Model 770 Home Uterine Activity Monitoring System for use in women with a previous preterm

delivery to aid in the detection of preterm labor. Accordingly, the order is being codified in the Code of Federal Regulations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device.

DATES: This rule is effective April 9, 2001. The reclassification was effective January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976