

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558 9836 '01 SEP 13 P1:45

DMB

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New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 30 approved new animal drug applications (NADAs) from Pfizer, Inc., to Phibro Animal Health, Inc. The technical amendments made by this final rule are intended to provide accuracy and clarity to the agency's regulations.

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-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, has informed FDA that it has transferred ownership of, and all rights and interest in, the following NADAs to Phibro Animal Health, Inc., One Parker Plaza, Fort Lee, NJ 07024:

NADA No.	Product Name
32-704	Bloat Guard® Top Dressing
35-287	OM-5 Premix
38-281	Bloat Guard® Liquid Premix
41-061	Mecadox® Premix 10
43-290	Banminth® Premix 80
46-668	Penicillin G Procaine 50% and 100% Type A Medicated Articles
91-467	Stafac® 20, 500 Type A Medicated Articles
91-513	Stafac® Type A Medicated Articles
92-286	CTCL 10, 20, 30, 50, 70 Type A Medicated Article
92-287	CTCL 50 MR, 100 MR Type A Medicated Article
92-444	Rumatel® Premix 88
92-955	Mecadox®/Banminth®
98-431	Tylan® 10 Premix
99-006	Terramycin®/Coban®
101-666	Terramycin®/Robenz®
110-047	Banminth®/Tylan®
116-044	Banminth®/Lincomix®
120-724	Stafac®/Coban®/3-Nitro®
122-481	Stafac®/Coban®
122-608	Stafac®/Avatec®
122-822	Stafac®/Amprol HI-E®

NADA No.	Product Name
138-828	Stafac®/Biocox®
138-953	Stafac®/Biocox®/3-Nitro®
140-448	Biocox®/Terramycin®
140-940	Aviax® Type A Medicated Article
140-998	V-Max Type A Medicated Article
141-058	Aviax®/BMD®/3-Nitro®
141-058	Aviax®/BMD®/3-Nitro®
141-065	Aviax®/BMD®
141-066	Aviax®/3-Nitro®
141-114	Aviax®/Stafac®

Accordingly, the agency is amending the regulations in §§ 520.1840, 558.58, 558.115, 558.128, 558.198, 558.311, 558.355, 558.360, 558.435, 558.450, 558.460, 558.465, 558.485, 558.515, 558.550, 558.555, 558.625, and 558.635 (21 CFR 520.1840, 558.58, 558.115, 558.128, 558.198, 558.311, 558.355, 558.360, 558.435, 558.450, 558.460, 558.465, 558.485, 558.515, 558.550, 558.555, 558.625, and 558.635) to reflect the transfer of ownership. In addition, §§ 520.1840 and 558.485 are being revised to reflect current format.

Section 558.450 is also being amended to remove the entries for combination uses of oxytetracycline (OTC) with monensin, provided under NADA 99-066, because they are redundant with entries in § 558.355. The entry for the use of 400 grams per (g/) ton OTC with 90 to 110 g/ton monensin in § 558.450(d)(1)(vi) is an error created during prior revisions (61 FR 51588, Oct. 3, 1996). The correct drug levels, 200 g/ton OTC with 90 to 110 g/ton monensin, for the same indications are codified in § 558.355(f)(1)(viii). The entry for the use of 500 g/ton OTC with 90 to 110 g/ton monensin in § 558.450(d)(1)(vii) is redundant with § 558.355(f)(1)(xxii).

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 520

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 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

2. Section 520.1840 is amended by revising paragraphs (a), (b), and (c) to read as follows.

§ 520.1840 Poloxalene.

(a) *Specifications.* Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000069 for use as in paragraphs (d)(1) and (d)(3) of this section.

(2) No. 017800 for use as in paragraph (d)(4) of this section.

(3) No. 036904 for use as in paragraph (d)(2) of this section.

(4) No. 066104 for use as in paragraph (d)(3) of this section.

(c) [Reserved]

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PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.58 [Amended]

4. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1)(iii) under the "Limitations" column in the entry for "Virginiamycin 15" by removing "000069" and by adding in its place "066104".

§ 558.115 [Amended]

5. Section 558.115 *Carbadox* is amended in paragraph (a) by removing "000069" and by adding in its place "066104".

§ 558.128 [Amended]

6. Section 558.128 *Chlortetracycline* is amended in paragraph (a)(1) by removing "000069, 046573, and 053389" and by adding in its place "046573, 053389, and 066104"; and in the table in paragraph (d)(1) under the "Sponsor" column by removing "000069" wherever it occurs and by adding in its place in numerical sequence "066104".

§ 558.198 [Amended]

7. Section 558.198 *Diclazuril* is amended in the table in paragraphs (d)(1)(iv) and (d)(1)(v) by removing "000069" under the "Limitations" column and by adding in its place "066104".

§ 558.311 [Amended]

8. Section 558.311 *Lasalocid* is amended in paragraph (b)(2) by removing "000069" and by adding in its place "066104" and in the table in paragraph (e)(1)(xv) in the entry for "Virginiamycin 10 to 20" under the "Limitations" column by removing "000069" and by adding in its place "066104".

§ 558.355 [Amended]

9. Section 558.355 *Monensin* is amended in paragraphs (b)(5), (b)(12), (f)(1)(xxii)(b), and (f)(2)(iv)(b) by removing "000069" and by adding in its place "066104"; in paragraphs (f)(1)(xiii)(b)

and (f)(1)(xxi)(b) by removing "000007" and by adding in its place "066104"; and in paragraph (f)(1)(xx)(b) by removing "as monensin sodium; as roxarsone" and by adding in its place "as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as virginiamycin provided by No. 066104 in § 510.600(c) of this chapter; roxarsone".

§ 558.360 [Amended]

10. Section 558.360 *Morantel tartrate* is amended in paragraph (a) by removing "000069" and by adding in its place "066104".

§ 558.435 [Amended]

11. Section 558.435 *Oleandomycin* is amended in paragraph (a) by removing "000069" and by adding in its place "066104".

§ 558.450 [Amended]

12. Section 558.450 *Oxytetracycline* is amended in table 1 in paragraph (d)(1) by removing the entries for "Monensin 90 to 110 g/ton" in paragraphs (d)(1)(vi) and (d)(1)(vii); in paragraph (d)(1)(vii) in the entry for "Salinomycin 40 to 60 g/ton" by removing "000069" under the "Sponsor" column and by adding in its place in numerical sequence "066104".

§ 558.460 [Amended]

13. Section 558.460 *Penicillin* is amended in paragraph (b) by removing "000069" and by adding in its place "066104".

§ 558.465 [Amended]

14. Section 558.465 *Poloxalene free-choice liquid Type C feed* is amended in paragraph (a) by removing "000069" and by adding in its place "066104".

15. Section 558.485 is amended by revising paragraphs (a), (b), and (d)(1) to read as follows:

§ 558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 9.6, 19.2, 48, or 80 grams per pound pyrantel tartrate.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section:

(1) No. 066104: 9.6, 19.2, and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2) No. 001800: 9.6 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(3) Nos. 010439, 011490, 011749, 016968, 017473, 017519, 017790, 043733, 049685, 050568, 050639, and 051359: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(4) No. 021676: 19.2 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(5) No. 017800: 19.2 and 48 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) Nos. 034936 and 046987: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(7) Nos. 000069, 017135, and 062240: 48 grams per pound for use as in paragraph (e)(2) of this section.

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(d) *Special considerations.* (1) See § 500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

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§ 558.515 [Amended]

16. Section 558.515 *Robenidine hydrochloride* is amended in the table in paragraph (d) in the entry for "Oxytetracycline 400" under the "Sponsor" column by removing "000069" and by adding in its place "066104".

§ 558.550 [Amended]

17. Section 558.550 *Salinomycin* is amended in paragraphs (d)(1)(x)(c) and (d)(1)(xii)(c) by removing "053571" and by adding in its place "066104".

18. Section 558.555 is amended by revising paragraph (a); by removing paragraph (c); by redesignating paragraph (b) as paragraph (c); in paragraph (d) by removing "000069" wherever it appears and by adding in its place "066104"; and by adding new paragraph (b) to read as follows:

§ 558.555 Semduramicin.

(a) *Specifications.* Type A medicated article containing 22.7 grams per pound (50 grams per kilogram) semduramicin sodium.

(b) *Approvals.* See No. 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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§ 558.625 [Amended]

19. Section 558.625 *Tylosin* is amended in paragraph (b)(25) by removing "000069" and by adding in its place "066104".

§ 558.635 [Amended]

20. Section 558.635 *Virginiamycin* is amended in paragraph (a)(1) by removing "000069" and by adding in its place "066104".