(d)(1)(ii), (d)(1)(iii), and (d)(3) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.55 [Amended]

19. Section 558.55 *Amprolium* is amended in the table in paragraphs (d)(2)(iii) by removing ''012799'' wherever it appears under the ''Limitations'' and ''Sponsor'' columns and by adding in its place ''057926''.

§ 558.58 [Amended]

20. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraphs (d)(1)(ii) and (d)(1)(iii) by removing ''012799'' wherever it appears in the ''Limitations'' column and by adding in its place ''057926''.

§ 558.95 [Amended]

21. Section 558.95 *Bambermycins* is amended in paragraphs (a)(1), (a)(2), (a)(5), (d)(1)(vi)(*b*), and (d)(1)(vii)(*b*) by removing ''012799'' and by adding in its place ''057926''; and in paragraphs (d)(1)(xi)(*b*), and (d)(1)(xii)(*b*) by removing ''012799 and 046573'' and by adding in its place ''046573 and 057926''.

§ 558.198 [Amended]

22. Section 558.198 *Diclazuril* is amended in the table in paragraphs (d)(1)(iii) by removing ''012799'' under the ''Limitations'' column and by adding in its place ''057926.''

§ 558.258 [Amended]

23. Section 558.258 *Fenbendazole*is amended in paragraph (a) by removing ''012799'' and by adding in its place ''057926''.

§ 558.265 [Amended]

24. Section 558.265 *Halofuginone hydrobromide* is amended in paragraph (a) by removing ''012799'' and by adding in its place ''057926''.

§ 558.355 [Amended]

25. Section 558.355 *Monensin* is amended in paragraphs (b)(10), (f)(2)(v)(*b*), and (f)(2)(vi)(*b*) by removing ''012799'' and by adding in its place ''057926''.

§ 558.363 [Amended]

26. Section 558.363 *Narasin* is amended in paragraphs (a)(4), (a)(5), (d)(1)(vii)(B), and (d)(1)(xii)(B) by removing ''012799'' and by adding in its place ''057926''.

§ 558.366 [Amended]

27. Section 558.366 *Nicarbazin* is amended in the table in paragraph (c) in the entry for ''Bambermycins 1 to 2'' under the ''Sponsor'' column by removing ''012799'' and by adding in its place ''057926''.

§ 558.550 [Amended]

28. Section 558.550 *Salinomycin* is amended in paragraph (a)(2) by removing ''012799'' and by adding in its place ''057926''; and in paragraphs (d)(1)(xv)(*c*) and (d)(1)(xvi)(*c*) by removing ''012799 and 046573'' and by adding in its place ''046573 and 057926''.

Dated: August 31, 2001.

Claire M. Lathers,

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

[FR Doc. 01–23043 Filed 9–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

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 September 17, 2001.

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®
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]

* * * * *

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.

* * * * *

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

* * * * *

§ 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.

* * * * *

§ 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''.

Dated: August 31, 2001.

Claire M. Lathers,

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

[FR Doc. 01–23044 Filed 9–14–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301164; FRL–6798–5]

RIN 2070–AB78

Fluroxypyr 1-Methylheptyl Ester; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr in or on grass, forage and grass, hay and modifies the existing permanent tolerances for milk and for kidney of cattle, goat, hog, horse, and sheep. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pastures and rangeland. This regulation establishes maximum permissible levels for residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr in these food commodities. The tolerances will expire and are revoked on June 30, 2003.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301164, must be received by EPA on or before November 16, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301164 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367, and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301164. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for the combined residues of the herbicide fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and