(m) For purposes of this section, rights to, or obligations of, research and development reimbursement, maintenance cost reimbursement, or user fees cannot be transferred from any individual or entity unless specifically approved in writing by the Board.

§ 400.713 Non-Reinsured supplemental (NRS) policy.

(a) The reinsured company must submit three copies of the new or revised NRS policy and related materials to the Deputy Administrator, Research and Development (or successor), Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133–4676 for review, approval or disapproval at least 90 days prior to the first sales closing date applicable to the policy reinsured by FCIC.

(b) FCIC will approve the NRS policy if it does not increase or shift risk to the underlying policy or plan of insurance reinsured by FCIC, affect any rights of the insured with respect to the underlying reinsured policy or plan of insurance, or cause disruption in the marketplace for products reinsured by FCIC. Marketplace disruption includes adversely affecting sales or administration of the underlying reinsured policy, undermining producers' confidence in the Federal crop insurance program, decreasing the producer's willingness or ability to use Federally reinsured risk management products, or harming public perception of the Federal crop insurance program.

(c) Failure to timely submit the NRS policy to FCIC will result in the denial of reinsurance and subsidy for all policies reinsured by FCIC for which the insured has obtained the NRS policy.

Signed in Washington, D.C. on September 12, 2001.

Phyllis W. Honor,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 01–23157 Filed 9–12–01; 4:21 pm]

BILLING CODE 3410–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

New Animal Drugs; Change of Sponsor; Technical Amendment

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 43 approved new animal drug applications (NADAs) and 16 approved abbreviated new animal drug applications (ANADAs) from Hoechst Roussel Vet to Intervet, Inc. Technical amendments are also being made. This action is being taken to improve the accuracy of 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: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, has informed FDA that it has transferred ownership of, and all rights and interest in, the following NADAs and ANADAs to Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966.

NADA Number	Product Name
34–478	LASIX® Injection
34–621	LASIX® Tablets and Boluses
44–759	FLAVOMYCIN® Type A Medicated Article
45–188	LASIX® Packets
95–543	AMPROL HI–E®/FLAVOMYCIN®
95–547	AMPROL HI–E®/FLAVOMYCIN®/3–NITRO®
95–548	AMPROL®/3–NITRO®/FLAVOMYCIN®
95–549	AMPROL®/3–NITRO®/FLAVOMYCIN®
98–340	FLAVOMYCIN®/Monensin
98–341	FLAVOMYCIN®/3–NITRO®/COBAN®
101–628	FLAVOMYCIN®/3–NITRO®/ZOALENE®
101–629	FLAVOMYCIN®/ZOALENE®
102–380	LASIX® Syrup
104–494	PANACUR® 10% Suspension
111–278	PANACUR® Granules 22%
120–648	PANACUR®/SAFE–GUARD® Paste
121–473	PANACUR® Granules 22%
128–620	PANACUR®/SAFE–GUARD® 10% Suspension
130–185	FLAVOMYCIN®/Amprolium
130–661	FLAVOMYCIN®/CARB–O–SEP®
130–951	STENOROL® Type A Medicated Article
131–310	REGU–MATE® Solution
131–675	SAFE–GUARD® Type A Medicated Article
132–872	PANACUR®/SAFE–GUARD® 10% Paste
137–483	FLAVOMYCIN®/STENOROL®
137–600	SAFE–GUARD® Type A Medicated Article
138–612	FINAPLIX®–S; FINAPLIX®–H Implants
139–189	SAFE–GUARD® ENPROAL Feedblocks
139–473	STENOROL®/STAFAC®
140–339	FLAVOMYCIN®/NICARB®
140–340	STENOROL®/LINCOMIX®
140–533	STENOROL®/3–NITRO®/BMD®
140–584	STENOROL®/BMD®
140–824	STENOROL® Type A Medicated Article
140–843	MONTEBAN®/FLAVOMYCIN®/3–NITRO®
140–845	FLAVOMYCIN®/MONTEBAN®
140–897	REVALOR®–S; REVALOR®–G Implants

NADA Number	Product Name
140–918	STENOROL®/FLAVOMYCIN®
140–919	STENOROL®/BMD®
140–954	SAFE–GUARD® Type A/LINCOMIX®
140–992	REVALOR®–200; REVALOR®–H Implants
141–034	GAINPRO® Type A Medicated Article
141–129	AVATEC®/FLAVOMYCIN®
200–075	SACOX® Type A Medicated Article
200–080	SACOX®/3–NITRO®/FLAVOMYCIN®
200–081	SACOX®/3–NITRO®/BMD®
200–082	SACOX®/BMD®
200–083	SACOX®/FLAVOMYCIN®
200–086	SACOX®/ALBAC®/3–NITRO®
200–089	SACOX®/BACIFERM®
200–090	SACOX®/LINCOMIX®/3–NITRO®
200–091	SACOX®/3–NITRO®/AUREOMYCIN®
200–092	SACOX®/STAFAC®
200–093	SACOX®/LINCOMIX®
200–094	SACOX®/STAFAC®/3–NITRO®
200–095	SACOX®/AUREOMYCIN®
200–096	SACOX®/TERRAMYCIN®
200–097	SACOX®/3–NITRO®
200–143	SACOX®/3–NITRO®/BACIFERM®

Accordingly, the agency is amending the regulations in 21 CFR 520.48, 520.905a, 520.905b, 520.905c, 520.905d, 520.905e, 520.1010a, 520.1010b, 520.1010c, 522.1010, 522.2476, 522.2477, 558.55, 558.58, 558.95, 558.198, 558.258, 558.265, 558.355, 558.363, 558.366, and 558.550 to reflect the transfers of ownership. In addition, the sections in 21 CFR parts 520 and 522 are being revised to reflect current format.

Following the change of sponsor of these NADAs, Hoechst Roussel Vet is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove the entries for this sponsor.

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 and 522

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, 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 ''Hoechst Roussel Vet'' and in the table in paragraph (c)(2) by removing the entry for ''012799''.

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.

4. Section 520.48 is revised to read as follows:

§ 520.48 Altrenogest solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount.* 1.0 mL per 110 pounds body weight (0.044 mg per kilogram) daily for 15 consecutive days.

(2) *Indications for use.* For suppression of estrus in mares.

(3) *Limitations.* For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food.

§ 520.905a [Amended]

5. Section 520.905a *Fenbendazole suspension* is amended in paragraph (b) by removing ''012799'' and by adding in its place ''057926''.

§ 520.905b [Amended]

6. Section 520.905b *Fenbendazole granules* is amended in paragraph (b) by removing ''012799'' and by adding in its place ''057926''.

§ 520.905c [Amended]

7. Section 520.905c *Fenbendazole paste* is amended in paragraph (b) by removing ''012799'' and by adding in its place ''057926''.

§ 520.905d [Amended]

8. Section 520.905d *Fenbendazole powder* is amended in paragraph (b) by removing ''012799'' and by adding in its place ''057926''.

§ 520.905e [Amended]

9. Section 520.905e *Fenbendazole blocks* is amended in paragraph (b) by removing ''012799'' and by adding in its place ''057926''.

10. Section 520.1010 is revised to read as follows:

§ 520.1010 Furosemide.

(a) *Specifications.* (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use of dosage forms and strengths listed in

paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000093 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(B) of this section.

(3) No. 057926 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*. It is used as follows:

(1) *Cattle*—(i) *Amount*. 1 to 2 mg per pound (/lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) *Indications for use*. For treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations*. Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) *Dogs*—(i) *Amount*. 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use*—(A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) *Cats*—(i) *Amount*. 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use*. For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

§ 520.1010a [Removed]

11. Section 520.1010a *Furosemide tablets or boluses* is removed.

§ 520.1010b [Removed]

12. Section 520.1010b *Furosemide powder* is removed.

§ 520.1010c [Removed]

13. Section 520.1010c *Furosemide syrup* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

15. Section 522.1010 is revised to read as follows:

§ 522.1010 Furosemide.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of furosemide diethanolamine.

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

(1) No. 000010 for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 000864 for use as in paragraph (d)(2)(ii) of this section.

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

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) Amount. 1.25 to 2.5 mg per pound (/lb) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses*—(i) *Amount*. 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(ii) *Amount*. 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For treatment of acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(3) *Cattle*—(i) *Amount*. 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily at 12-hour intervals, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations*. Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

16. Section 522.2476 is revised to read as follows:

§ 522.2476 Trenbolone acetate.

(a) [Reserved]

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

(1) No. 021641 for use as in paragraphs (d)(1) and (d)(2) of this section.

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

(c) *Related tolerances*. See § 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*—(i) *Amount*. Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use*. For improved feed efficiency.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

(2) *Heifers fed in confinement for slaughter*—(i) Amount. Use last 63 days prior to slaughter.

(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

17. Section 522.2477 is amended by revising paragraph (b) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

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

(1) No. 021641 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B),

(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