

(c) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 526.1696c [Amended]

■ 9. In paragraph (b) of § 526.1696c, remove “033392” and in its place add “042791”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 11. In § 529.1940, in paragraphs (b) and (e)(1)(iii), remove “000009” and in its place add “054771”; in paragraph (c), remove “§ 556.540(a)” and in its place add “§ 556.540”; and add paragraph (e)(1)(ii)(D) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(e) * * *

(1) * * *

(ii) * * *

(D) For induction of estrous cycles in anestrous lactating dairy cows.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 13. In paragraph (d)(5) of § 558.95, redesignate paragraphs (d)(5)(iii) through (d)(5)(x) as paragraphs (d)(5)(iv)

through (d)(5)(xi); and add new paragraph (d)(5)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(iii) Clopidol as in § 558.175.

* * * * *

■ 14. In § 558.175:

■ a. Redesignate paragraph (d)(9) as paragraph (d)(11).

■ b. Redesignate paragraphs (d)(5) through (d)(8) as paragraphs (d)(6) through (d)(9).

■ c. Add new paragraphs (d)(5) and (d)(10).

The additions read as follows:

§ 558.175 Clopidol.

* * * * *

(d) * * *

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(5) 113.5	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age	016592
(10) 227	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age	016592

Dated: January 27, 2014.
Bernadette Dunham,
 Director, Center for Veterinary Medicine.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524, 526, and 529

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect a change of sponsor for 54 approved new animal drug applications (NADAs) and 1 approved abbreviated new animal drug application (ANADA) for topical, intramammary, and certain other dosage form new animal drug products from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc.

DATES: This rule is effective February 27, 2014.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl.,

Rockville, MD 20855; 240-276-8300, steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 E. 42d St., New York, NY 10017, and its wholly owned

subsidiaries Alpharma, LLC; Fort Dodge Animal Health, Division of Wyeth; Fort Dodge Animal Health, Division of Wyeth Holdings Corp.; and its division, Pharmacia & Upjohn Co., have informed FDA that they have transferred

ownership of, and all rights and interest in, the 54 approved NADAs and 1 approved ANADA in table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007.

TABLE 1—NADAS AND ANADA TRANSFERRED FROM PFIZER, INC., TO ZOETIS, INC.

File No.	Product name
008-763	TERRAMYCIN (oxytetracycline hydrochloride) Ophthalmic Ointment with Polymyxin.
009-035	OPHTHAINE (proparacaine hydrochloride) Solution.
009-782	NOLVASAN (chlorhexidine acetate) Antiseptic Ointment.
009-809	NOLVASAN CAP-TABS (chlorhexidine acetate) Tablets.
010-434	NOLVASAN (chlorhexidine acetate) Suspension.
010-524	NEO-CORTEF with Tetracaine (neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride) Ointment.
011-703	NEO-DELTA CORTEF with Tetracaine (neomycin sulfate, prednisolone acetate, tetracaine hydrochloride) Ointment.
012-258	PANOLOG (triamcinolone acetonide, nystatin, thiostrepton, neomycin sulfate) Ointment.
012-991	KOPERTOX (copper naphthenate) Topical.
013-293	TERRA-CORTRIL (oxytetracycline hydrochloride and hydrocortisone) Topical Spray.
014-170	FLUOTHANE (halothane, USP).
015-433	NEO-PREDEF with Tetracaine (neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gammapiocolinium chloride) Ointment.
030-025	NEO-PREDEF with Tetracaine (neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride) Topical Ointment.
032-168	DOMOSO (dimethyl sulfoxide) Solution.
032-319	TOPAZONE (furazolidone) Aerosol Powder.
034-872	NEO PREDEF (neomycin sulfate and isoflupredone acetate) Ointment.
037-586	ERYTHROMAST 36 (erythromycin) Intramammary Infusion.
038-801	ANAPRIME (flumethasone, polymyxin B sulfate, and neomycin sulfate) Ophthalmic Solution.
042-661	KANTRIM (kanamycin sulfate) Ophthalmic Ointment.
042-883	KANTRIM (kanamycin sulfate) Ophthalmic Solution.
043-784	KANFOSONE (kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate) Ointment.
045-512	SYNOTIC (fluocinolone acetonide and dimethyl sulfoxide) Otic Solution.
047-334	SYNSAC (fluocinolone acetonide and dimethyl sulfoxide) Topical Solution.
047-925	DOMOSO (dimethyl sulfoxide) Gel.
047-997	AMPHODERM (kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate) Ointment.
049-725	ANAPRIME Ophthakote (flumethasone, polymyxin B sulfate, and neomycin sulfate) Ophthalmic.
049-726	OPTIPRIME OPTHAKOTE (neomycin sulfate and polymyxin B sulfate) Ophthalmic Solution.
055-072	ALBACILLIN (procaine penicillin G/novobiocin) Suspension for Intramammary Infusion.
055-095	TICILLIN (ticarcillin disodium) Powder for Intrauterine Infusion.
055-098	ALBADRY Plus (procaine penicillin G and novobiocin sodium) Suspension for Intramammary Infusion.
065-114	MYCITRACIN (bacitracin zinc, neomycin sulfate, and polymyxin B sulfate) Ophthalmic Ointment.
065-119	FORTE (neomycin sulfate, penicillin, polymyxin B, hydrocortisone) Topical Ointment.
065-122	TETRACYN (tetracycline hydrochloride) Ointment.
065-149	CHLOROMYCETIN (chloramphenicol) Ophthalmic Ointment.
091-534	NEO-DELTA CORTEF (prednisolone acetate and neomycin sulfate) Solution.
093-514	NEO-CORTEF (neomycin sulfate and hydrocortisone acetate) Ointment.
096-676	PANOLOG (triamcinolone acetonide, nystatin, thiostrepton, neomycin sulfate) Cream.
100-808	ALBAMAST (novobiocin sodium) Suspension for Intramammary Infusion.
102-511	BIODRY (novobiocin sodium) Suspension for Intramammary Infusion.
120-299	MITABAN (amitraz) Liquid Concentrate.
127-892	AMIGLYDE-V (amikacin sulfate) Intrauterine Infusion.
130-435	OXYMARINE (oxytetracycline hydrochloride) Fish Marker.
140-839	BACTODERM (mupirocin) Ointment.
140-844	TRAMISOL (levamisole) Pour-On Topical Solution.
140-879	DERMA 4 (nystatin, neomycin sulfate, thiostrepton, and triamcinolone acetonide) Ointment.
141-003	DERM-OTIC (nystatin, neomycin, thiostrepton, and triamcinolone acetonide) Ointment.
141-036	PIRSUE (pirlimycin hydrochloride) Intramammary Infusion.
141-082	DOXIROBE (doxycycline hyclate) Gel.
141-095	DECTOMAX (doramectin) Pour-on Solution.
141-152	REVOLUTION (selamectin) Topical Solution.
141-200	EAZI-Breed CIDR (progesterone) Cattle Insert.
141-238	SPECTRAMAST LC (ceftiofur hydrochloride) Sterile Suspension for Intramammary Infusion.
141-239	SPECTRAMAST DC (ceftiofur hydrochloride) Sterile Suspension for Intramammary Infusion.
141-302	EAZI-BREED CIDR (progesterone) Sheep Insert.
200-102	GENTAGLYDE (gentamicin sulfate) Solution.

Accordingly, the Agency is amending the regulations in 21 CFR parts 524, 526, and 529 to reflect these transfers of ownership. In addition, the regulations are being amended to make minor

corrections and to reflect a current format. This is being done to increase the accuracy and readability of the regulations.

In addition, FDA has noticed that certain sections of part 526 contain entries describing conditions of use for new animal drug products for which no NADA is approved. These errors were

introduced by the Agency during the 1992 recodification of the regulations for certifiable antibiotics (57 FR 37318, August 18, 1992). That rule did not identify whether particular regulations were the subject of an approved NADA and consequently resulted in codification of certain conditions of use for which there is no approved NADA. At this time, the Agency is amending the regulations to remove these entries. This action is being taken to improve the accuracy of the regulations.

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 in 21 CFR Parts 524, 526, and 529

Animal drugs.

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 524, 526, and 529 are amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 524.86, revise the section heading, and paragraphs (b) and (c)(3) to read as follows:

§ 524.86 Amitraz.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) * * *

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

■ 3. In § 524.154, revise the section heading, redesignate paragraphs (a) and (b) as paragraphs (b) and (c); add new paragraph (a); and revise paragraph (b), and the introductory text in paragraph (c) to read as follows:

§ 524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains:

(1) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate; or

(2) 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(2) Nos. 000061 and 043264 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(c) *Conditions of use in dogs and cats.* * * *

* * * * *

■ 4. In § 524.155, revise the section heading, redesignate paragraphs (a) and (b) as paragraphs (b) and (c); add new paragraph (a); and revise paragraph (b), and the introductory text in paragraph (c) to read as follows:

§ 524.155 Bacitracin, neomycin, polymyxin B, and hydrocortisone ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 400 units of bacitracin zinc, 5 milligrams (mg) of neomycin sulfate (equivalent to 3.5 mg of neomycin sulfate), 10,000 units of polymyxin B sulfate, and 10 mg of hydrocortisone.

(b) *Sponsors.* See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats.* * * *

* * * * *

§ 524.390 [Amended]

■ 5. In § 524.390, revise paragraphs (b) and (c)(3) to read as follows:

§ 524.390 Chloramphenicol ophthalmic ointment.

* * * * *

(b) *Sponsors.* See Nos. 043264 and 054771 in § 510.600(c) of this chapter.

(c) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the use of this drug in food-producing animals.

§ 524.402 [Amended]

■ 6. In paragraph (b) of § 524.402, remove “000856” and in its place add “054771”.

■ 7. In § 524.450, revise the section heading, and paragraphs (b) and (c)(3) to read as follows:

§ 524.450 Clotrimazole.

* * * * *

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter.

(c) * * *

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

§ 524.463 [Amended]

■ 8. In paragraph (b) of § 524.463, remove “000856, 017135, and 058829” and in its place add “017135, 054771, and 058829”.

■ 9. In § 524.575, revise paragraphs (c)(1) and (c)(3) to read as follows:

§ 524.575 Cyclosporine ophthalmic ointment.

* * * * *

(c) * * *

(1) *Amount.* Apply a ¼-inch strip of ointment directly on the cornea or into the conjunctival sac of the affected eye(s) every 12 hours.

* * * * *

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

■ 10. Revise § 524.660 to read as follows:

§ 524.660 Dimethyl sulfoxide.

(a) *Specifications.*—(1) Each milliliter (mL) of solution contains 90 percent dimethyl sulfoxide and 10 percent water.

(2) Each milliliter (mL) of gel product contains 90 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and dogs.*—(1) *Amount.*—(i) *Horses.* Apply topically two to three times daily in an amount not to exceed 100 mL per day. Total duration of therapy should not exceed 30 days.

(ii) *Dogs.* Apply topically three to four times daily in an amount not to exceed 20 mL per day. Total duration of therapy should not exceed 14 days.

(2) *Indications for use.* To reduce acute swelling due to trauma.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§§ 524.660a and 524.660b [Removed]

■ 11. Remove §§ 524.660a and 524.660b.

■ 12. In § 524.770, in paragraph (b), remove “000069” and in its place add “054771”; and revise paragraph (e)(3) to read as follows:

§ 524.770 Doramectin.

* * * * *

(e) * * *

(3) *Limitations.* Do not slaughter cattle within 45 days of latest treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 13. In § 524.802, revise the section heading and paragraph (c)(3) to read as follows:

§ 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.

* * * * *

(c) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

■ 14. In § 524.900, remove paragraph (a); redesignate paragraphs (b) through (f) as paragraphs (a) through (e); and revise newly redesignated (e) to read as follows:

§ 524.900 Famphur.

* * * * *

(e) *Conditions of use*—(1) *Amount.* Apply 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, from the shoulder to the tail head as a single treatment. Apply as soon as possible after heel fly activity ceases.

(2) *Indications for use in beef and nonlactating dairy cattle.* For control of cattle grubs and to reduce cattle lice infestations.

(3) *Limitations.* Do not slaughter within 35 days after treatment. Do not use on lactating dairy cows or dry dairy cows within 21 days of freshening, calves less than 3 months old, animals stressed from castration, overexcitement or dehorning, sick or convalescent animals. Animals may become dehydrated and under stress following shipment. Do not treat until they are in good condition. Brahman and Brahman crossbreeds are less tolerant of cholinesterase-inhibiting insecticides than other breeds. Do not treat Brahman bulls. Swine should be eliminated from area where runoff occurs.

■ 15. Revise § 524.920, to read as follows:

§ 524.920 Fenthion.

(a) *Specifications.* (1) The drug is a liquid containing:

- (i) 3 percent of fenthion; or
- (ii) 20 percent fenthion.

(2) The drug is a solution containing either 5.6 or 13.8 percent fenthion. Each concentration is available in 2 volumes which are contained in single-dose applicators.

(b) *Sponsor.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000859 for use of product described in paragraph (a)(1)(i) as in paragraph (d)(1) of this section.

(2) No. 000859 for use of product described in paragraph (a)(1)(ii) as in paragraph (d)(2) of this section.

(3) No. 000859 for use of products described in paragraph (a)(2) as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See 40 CFR 180.214.

(d) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* It is used at the rate of one-half fluid ounce per 100 pounds of body weight applied topically on the backline of the animal. Only one application per season should be made for grub control and this will also provide initial control of lice. A second application for lice control may be made if animals become reinfested, but no sooner than 35 days after the first treatment. Proper timing of treatment is important for grub control; cattle should be treated as soon as possible after heel-fly activity ceases.

(ii) *Indications for use.* For the control of grubs and lice in beef and nonlactating cattle.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Cattle should not be slaughtered within 35 days following a single treatment. If a second application is made for lice control, cattle should not be slaughtered within 45 days of the second treatment. The drug must not be used within 28 days of freshening of dairy cattle. If freshening should occur within 28 days after treatment, do not use milk as human food for the balance of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; or sick, convalescent, or stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious infectious diseases.

(2) *Beef cattle and dairy cattle not of breeding age*—(i) *Amount.* It is administered as a single, topical application placed on the backline of animals as follows: For animals weighing 150 to 300 pounds, apply 4 milliliters (mL); for animals weighing 301 to 600 pounds, apply 8 mL; for animals weighing 601 to 900 pounds, apply 12 mL; for animals weighing 901 to 1,200 pounds, apply 16 mL; and for animal weighing over 1,200 pounds, apply 20 mL. For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. A second application is required for animals heavily infested with lice or for those which become reinfested. A second application should be made no sooner than 35 days after the first treatment.

(ii) *Indications for use.* For control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting

drugs, pesticides, or chemicals. Host-parasite reactions such as bloat, salivation, staggering and paralysis may sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gullet, or while the northern cattle grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated before these stages of grub development. Consult your veterinarian, extension livestock specialist, or extension entomologist regarding the timing of treatment. If it is impossible to determine the area from which the cattle came and/or exact stage of the grubs, it is recommended that the cattle receive only a maintenance ration of low-energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gullet. Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases. Do not slaughter within 45 days of treatment.

(3) *Dogs*—(i) *Amount.* Four to 8 milligrams per kilogram of body weight. Apply the contents of the proper size, single-dose tube directly to one spot on the dog's skin.

(ii) *Indications for use.* For flea control on dogs only.

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

■ 16. In § 524.960, in paragraph (b), remove “000856” and in its place add “054771”; and revise the section heading and paragraph (c)(3) to read as follows:

§ 524.960 Flumethasone, neomycin, and polymyxin B ophthalmic solution.

* * * * *

(c) * * *

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

§ 524.981 [Removed and Reserved]

■ 17. Remove and reserve § 524.981.

■ 18. In § 524.981a, revise the section heading, the introductory text in paragraph (c), and paragraphs (c)(1) and (c)(2) to read as follows:

§ 524.981a Fluocinolone cream.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount is applied to the affected area two or three times daily.

(2) *Indications for use.* For the relief of pruritis and inflammation associated

with certain superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical burns and physical abrasions.

* * * * *

■ 19. In § 524.981b, revise the section heading, paragraph (a), the introductory text in paragraph (c), and paragraphs (c)(1) and (c)(2) to read as follows:

§ 524.981b Fluocinolone solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount of solution is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses.

(ii) *Cats.* For the relief of pruritis and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses.

* * * * *

■ 20. In § 524.981c, revise the section heading, the introductory text in paragraph (c), and paragraphs (c)(1) and (c)(2) to read as follows:

§ 524.981c Fluocinolone and neomycin cream.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and nonspecific dermatoses.

(ii) *Dogs and cats.* Used in the treatment of wound infections.

* * * * *

■ 21. Revise § 524.981d to read as follows:

§ 524.981d Fluocinolone and dimethyl sulfoxide solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 1 to 2 milliliters into each anal sac following expression of anal sac contents.

(2) *Indications for use.* For the relief of impaction commonly present in

apparently normal anal sacs, for the reversal of inflammatory changes associated with abnormal anal sacs, and to counteract the offensive odor of anal sac secretions.

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

■ 22. Revise § 524.981e to read as follows:

§ 524.981e Fluocinolone and dimethyl sulfoxide otic solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 60 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters.

(2) *Indications for use.* For the relief of pruritis and inflammation associated with acute and chronic otitis.

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

■ 23. In § 524.1005, in paragraph (b)(1), remove “053501” and in its place add “054771”; in paragraph (c)(3), remove the last sentence and in its place add “Do not use in horses intended for human consumption.”; and revise the section heading to read as follows:

§ 524.1005 Furazolidone powder.

* * * * *

■ 24. In § 524.1044, revise the section heading to read as follows:

§ 524.1044 Gentamicin ophthalmic and topical dosage forms.

■ 25. In § 524.1044b, revise the section heading to read as follows:

§ 524.1044b Gentamicin and betamethasone otic solution.

* * * * *

■ 26. In § 524.1044c, revise the section heading to read as follows:

§ 524.1044c Gentamicin ophthalmic ointment.

* * * * *

■ 27. In § 524.1044d, revise the section heading and paragraph (c) to read as follows:

§ 524.1044d Gentamicin and betamethasone ointment.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount*—(i) *Otitis externa.* Instill 3 to 8 drops into the ear canal twice daily for 7 days.

(ii) *Infected superficial lesions.* Apply to cover the treatment area twice daily for 7 to 14 days.

(2) *Indications for use.* For the treatment of acute and chronic otitis externa and infected superficial lesions caused by bacteria sensitive to gentamicin.

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

■ 28. In § 524.1044e, revise the section heading and paragraph (c) to read as follows:

§ 524.1044e Gentamicin spray.

* * * * *

(c) *Conditions of use in cattle*—(1) *Amount.* Hold the sprayer upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pump once. Treat once daily for up to 3 days.

(2) *Indications for use.* For the treatment of pinkeye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*.

(3) *Limitations.* Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce similar signs. If conditions persists or increases, discontinue use and consult a veterinarian.

■ 29. In § 524.1044g, remove the second occurrence of paragraph (b)(3); and revise the section heading to read as follows:

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

* * * * *

■ 30. In § 524.1044h, revise the section heading and add paragraph (c)(3) to read as follows:

§ 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

* * * * *

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

■ 31. In § 524.1132, revise the section heading to read as follows:

§ 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.

* * * * *

■ 32. Revise § 524.1200a to read as follows:

§ 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 3.5 milligrams kanamycin activity as kanamycin sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) *Indications for use.* For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

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

■ 33. Revise § 524.1200b to read as follows:

§ 524.1200b Kanamycin ophthalmic solution.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams kanamycin activity as kanamycin sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as frequently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) *Indications for use.* For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

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

■ 34. Revise § 524.1204 to read as follows:

§ 524.1204 Kanamycin, amphotericin, and hydrocortisone ointment.

(a) *Specifications.* Each gram of ointment contains 5 milligrams kanamycin activity as kanamycin sulfate, 5 milligrams of amphotericin activity as the calcium salt, and 10 milligrams of hydrocortisone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply to the affected areas of the skin at least twice daily. In severe or widespread lesions it may be desirable to apply the ointment more than twice daily. After some

improvement is observed, treatment can usually be reduced to once daily.

(2) *Indications for use.* For the treatment of acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcers, superficial wounds, and superficial abscesses associated with bacterial infections caused by organisms susceptible to one or both antibiotics.

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

■ 35. In § 524.1240, revise paragraph (b) to read as follows:

§ 524.1240 Levamisole.

* * * * *

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 36. In § 524.1446, revise the section heading to read as follows:

§ 524.1446 Milbemycin otic solution.

* * * * *

§ 524.1465 [Amended]

■ 37. In paragraph (b) of § 524.1465, remove “000069, 025463, 026637, and 051672” and in its place add “025463, 026637, 051672, and 054771”.

■ 38. In § 524.1484, revise the section heading to read as follows:

§ 524.1484 Neomycin ophthalmic and topical dosage forms.

* * * * *

■ 39. In § 524.1484b, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484b Neomycin, isoflupredone, tetracaine, and myristyl-gamma-picolinium powder.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses, dogs, and cats*—(1) *Amount.* Apply to affected areas as a dusting powder.

(2) *Indications for use.* For the treatment or as adjunctive therapy of certain ear and skin conditions caused by or associated with neomycin-susceptible organisms and/or allergy; as a superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable; as a dusting powder following amputation of tails, claws, and dewclaws and following ear trimming, castrating, and such surgical procedures as ovariectomies. For the treatment of acute otitis externa, acute moist dermatitis, and interdigital dermatitis in dogs.

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

■ 40. In § 524.1484c, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484c Neomycin, isoflupredone, and tetracaine ointment.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(2) *Indications for use.* For the treatment of acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

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

■ 41. In § 524.1484d, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484d Neomycin, hydrocortisone, and tetracaine otic ointment.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Instill a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily.

(2) *Indications for use.* For the treatment of ear canker and other inflammatory conditions of the external ear canal, acute otitis externa and, to a lesser degree, chronic otitis externa.

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

■ 42. In § 524.1484e, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484e Neomycin and polymyxin B ophthalmic solution.

* * * * *

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1 to 2 drops per eye every 6 hours.

(2) *Indications for use*. For the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis.

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

■ 43. In § 524.1484f, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484f Neomycin, prednisolone, and tetracaine otic suspension.

* * * * *

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Instill 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use*. For the treatment of acute otitis externa and, to a lesser degree, chronic otitis externa; as treatment or adjunctive therapy of certain ear conditions caused by or associated with neomycin-susceptible organisms and/or allergy.

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

■ 44. In § 524.1484g, revise the section heading and paragraph (c) to read as follows:

§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.

* * * * *

(c) *Conditions of use in dogs and cats*—(1) *Amount*. In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (2 to 4 drops per square inch) twice daily. In treating otitis externa, instill 5 to 15 drops in the ear twice daily. Treat for up to 7 days.

(2) *Indications for use*. As an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa.

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

■ 45. In § 524.1484h, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.

* * * * *

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Rub a small amount into the affected area 1 to 3 times a day. After definite improvement, apply once daily or every other day.

(2) *Indications for use*. For the treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

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

■ 46. In § 524.1484i, revise the section heading and paragraphs (b) and (c) to read as follows:

§ 524.1484i Neomycin and hydrocortisone ointment.

* * * * *

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply 3 or 4 times daily into the conjunctival sac. With improvement, frequency may be reduced to 2 or 3 times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal 1 to 3 times daily.

(2) *Indications for use*. For the treatment of infections, allergic and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa.

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

■ 47. Add § 524.1484j to read as follows:

§ 524.1484j Neomycin and prednisolone ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate equivalent to 3.5 milligrams neomycin base.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition remains under control. Treatment may require from a few days to several weeks.

(2) *Indications for use*. For use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye, such as

those associated with allergic reactions or gross irritants.

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

■ 48. Add § 524.1484k to read as follows:

§ 524.1484k Prednisolone and neomycin suspension.

(a) *Specifications*. Each milliliter of suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. For beginning treatment of acute ocular inflammations place 1 or 2 drops in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, reduce the dosage to 1 drop 2 to 4 times daily. For otitis externa, place 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use*. For the treatment of treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa.

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

■ 49. In § 524.1580, revise the section heading to read as follows:

§ 524.1580 Nitrofurazone topical dosage forms.

* * * * *

§ 524.1580a [Removed]

■ 50. Remove § 524.1580a.

§ 524.1580b [Amended]

■ 51. Redesignate § 524.1580b as § 524.1580a; and in newly designated paragraph (b)(1), remove “000069,”.

§ 524.1580c [Amended]

■ 52. Redesignate § 524.1580c as § 524.1580b; in paragraph (b), remove “Nos. 000069 and 054628” and in its place add “No. 054628”; and in paragraphs (c)(2) and (c)(3), remove footnote 1.

§ 524.1580d [Removed]

■ 53. Remove § 524.1580d.

§ 524.1580e [Amended]

■ 54. Redesignate § 524.1580e as § 524.1580c; in paragraph (c)(1) and (c)(2), remove footnote 1; and revise the section heading to read as follows:

§ 524.1580c Nitrofurazone and butacaine ointment.

* * * * *

■ 55. In § 524.1600a, revise the section heading, paragraphs (b) and (c)(3) to read as follows:

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ointment.

* * * * *

(b) *Sponsors.* For petrolatum base ointments see Nos. 000856, 025463, 054771, and 054925 in § 510.600(c) of this chapter. For vanishing cream base ointments see Nos. 025463, 054771, and 054925.

(c) * * *

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

■ 56. In § 524.1600b, revise the section heading, and paragraph (c) to read as follows:

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ophthalmic ointment.

* * * * *

(c) *Conditions of use—(1) Dogs and cats—(i) Amount.* Apply 1 drop of ointment to the affected eye(s) 2 or 3 times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis.

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

(2) *Cattle—(i) Amount.* Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For infectious kerato-conjunctivitis (pinkeye).

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

■ 57. In § 524.1662, revise the section heading to read as follows:

§ 524.1662 Oxytetracycline ophthalmic and topical dosage forms.

* * * * *

■ 58. In § 524.1662a, in paragraph (b), remove “000069” and in its place add “054771”; and revise the section heading and paragraph (c) to read as follows:

§ 524.1662a Oxytetracycline and hydrocortisone spray.

* * * * *

(c) *Conditions of use in dogs and cats—(1) Amount.* A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds.

Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon after the initial favorable response has been obtained.

(2) *Indications for use.* For the relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions; for the prevention of bacterial infections in superficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus.

(3) *Limitations.* Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

■ 59. In § 524.1662b, in paragraph (b), remove “000069” and in its place add “054771”; and revise the section heading and paragraph (c) to read as follows:

§ 524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.

* * * * *

(c) *Conditions of use in dogs and cats—(1) Amount.* Administer topically to the eye two to four times daily.

(2) *Indications for use.* For the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms including ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

(3) *Limitations.* Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

§§ 524.1881, 524.1881a, and 524.1881b [Removed]

■ 60. Remove §§ 524.1881, 524.1881a, and 524.1881b.

§ 524.1883 [Removed]

■ 61. Remove § 524.1883.

■ 62. In § 524.1982, in paragraph (b), remove “053501” and in its place add “054771”; and revise the section heading and paragraph (c) to read as follows:

§ 524.1982 Proparacaine ophthalmic solution.

* * * * *

(c) *Conditions of use in dogs and cats—(1) Amount.* It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to ten drops in the ear; for nasal use, instill five to ten drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(2) *Indications for use.* For use as a topical ophthalmic anesthetic. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected; as an aid in the removal of foreign bodies from the nose and ear canal; as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(3) *Limitations.* Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

§ 524.2098 [Amended]

■ 63. In paragraph (b) of § 524.2098, remove “000069” and in its place add “No. 054771”.

■ 64. Revise § 524.2350 to read as follows:

§ 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate in an anhydrous cream base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Apply a small amount of the cream to

the affected areas once or twice a day for 2 to 4 weeks.

(2) *Indications for use.* For the treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypseum*.

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

■ 65. Revise § 524.2620 to read as follows:

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a) *Specifications*—(1) Each gram of liquid or aerosol contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Each gram of liquid or aerosol contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) in this section:

(1) No. 051079 for use of product described in paragraph (a)(1).

(2) No. 017135 for use of product described in paragraph (a)(2).

(c) *Conditions of use*—(1) *Amount.* Apply directly to the wound site.

(2) *Indications for use.* As an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate, and organic debris.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 526.313 [Amended]

■ 67. In paragraph (b) of § 526.313, remove “000009” and in its place add “054771”.

§ 526.464a [Amended]

■ 68. In § 526.464a, remove paragraph (d).

§ 526.464d [Removed]

■ 69. Remove § 526.464d.

§ 526.820 [Amended]

■ 70. In paragraph (b) of § 526.820, remove “No. 061623” and in its place add “Nos. 054771 and 061623”.

■ 71. In § 526.1130, revise the section heading to read as set forth below:

§ 529.1130 Hetacillin infusion.

* * * * *

■ 72. In § 526.1590, in paragraphs (a)(2) and (b)(2), remove “000009” and in its place add “054771”; and revise the section heading to read as follows:

§ 526.1590 Novobiocin infusion.

* * * * *

§ 526.1696d [Amended]

■ 73. In paragraph (b) of § 526.1696d, remove “000009” and in its place add “054771”.

§ 526.1810 [Amended]

■ 74. In paragraph (b) of § 526.1810, remove “000009” and in its place add “054771”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 75. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 76. In § 529.40, remove paragraph (c); redesignate paragraph (d) as paragraph (c); and revise newly redesignated paragraph (c)(3) to read as follows:

§ 529.40 Albuterol.

* * * * *

(c) * * *

(3) Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 529.56 [Amended]

■ 77. In paragraph (b) of § 529.56, remove “000856 and 000859” and in its place add “000859 and 054771”.

§ 529.400 [Amended]

■ 78. In § 529.400, revise the section heading; in paragraph (b), remove “000856” and in its place add “054771”; and in paragraphs (c)(1), (c)(2), and (c)(3), remove the footnote.

■ 79. Add § 529.778 to read as follows:

§ 529.778 Doxycycline.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(2) *Indications for use.* For treatment and control of periodontal disease.

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

§ 529.1044 [Amended]

■ 80. In § 529.1044, remove the word “sulfate” in the section heading.

■ 81. In § 529.1044a, revise the section heading and paragraph (b) to read as follows:

§ 529.1044a Gentamicin solution for infusion.

* * * * *

(b) *Sponsors.* See Nos. 000061, 000859, 054628, 054771, 057561, 058005, and 061623 in § 510.600(c) of this chapter.

* * * * *

■ 82. In § 529.1044b, revise the section heading and paragraph (c) to read as follows:

§ 529.1044b Gentamicin solution for dipping eggs.

* * * * *

(c) *Conditions of use in turkeys*—(1) *Amount.* The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the gentamicin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100 °F then immediately submerging them in gentamicin solution maintained at about 40 °F, keeping the eggs submerged for 10 to 15 minutes.

(2) *Indications for use.* As an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella Saintpaul*, and *Mycoplasma meleagridis*.

(3) *Limitations.* For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

■ 83. In § 529.1115, remove the footnote in paragraphs (c)(1), (c)(2), and (c)(3); and revise paragraphs (b) and (c)(3) to read as follows:

§ 529.1115 Halothane.

* * * * *

(b) *Sponsor.* See Nos. 012164 and 054771 in § 510.600(c) of this chapter.

(c) * * *

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 529.1660 [Amended]

■ 84. In § 529.1660, in paragraph (b)(1), remove “046573” and in its place add “054771”; and in paragraph (b)(2), remove “000069, 048164, and 059130”

and in its place add “048164, 054771, and 061623”.

§ 529.1940 [Amended]

■ 85. In paragraph (b) of § 529.1940, remove “000009” and in its place add “054771”.

■ 86. Revise § 529.2464 to read as follows:

§ 529.2464 Ticarcillin.

(a) *Specifications.* Each vial contains ticarcillin disodium powder equivalent to 6 grams of ticarcillin for reconstitution with 25 milliliters of sterile water for injection or sterile physiological saline.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 6 grams daily by intrauterine infusion for 3 consecutive days during estrus.

(2) *Indications for use.* For the treatment of endometritis caused by beta-hemolytic streptococci.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 87. Revise § 529.2503 to read as follows:

§ 529.2503 Tricaine methanesulfonate.

(a) *Specifications.* The drug is ethyl-m-amino-benzoate methanesulfonate.

(b) *Sponsor.* See Nos. 050378 and 051212 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* It is used as follows:

(i) *Fish.* The drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the

specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic coldblooded animals.* The drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

Dated: January 27, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA-2014-N-0002]

Zoetis Inc., et al.; Withdrawal of Approval of New Animal Drug Applications for Combination Drug Medicated Feeds Containing an Arsenical Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect the withdrawal approval of 69 new animal drug applications (NADAs) and 22 abbreviated new animal drug applications (ANADAs) for use of arsanilic acid, carbarsonne, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds. This action is being taken at the sponsor’s request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective March 10, 2014.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Recently, the Agency provided notice of the withdrawal of approval of NADAs for Type A medicated articles containing arsanilic acid, carbarsonne, and roxarsone and revoked applicable regulations for their conditions of use to manufacture single-ingredient medicated feeds in 21 CFR part 558 *New Animal Drugs For Use in Animal Feeds* (78 FR 70062, November 22, 2013; 78 FR 69992, November 22, 2013; 78 FR 70566, November 26, 2013; 78 FR 70496, November 26, 2013).

Subsequently, the following six sponsors of NADAs and ANADAs permitting use of arsanilic acid, carbarsonne, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds requested that FDA withdraw approval of their applications because these combination medicated feeds are no longer manufactured or marketed.

- Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following 39 NADAs and 11 ANADAs:

NADA/ANADA	Ingredient new animal drugs
040-435	3-NITRO (roxarsone)/DECCOX (decoquinatate).
041-178	Roxarsone/AMPROL Plus (amprolium and ethopabate)/LINCOMIX (lincomycin).
041-984	Roxarsone/ROFENAID (sulfadimethoxine/ormetoprim).
091-326	3-NITRO (roxarsone)/DECCOX (decoquinatate)/ALBAC (bacitracin zinc).
092-522	Roxarsone/COBAN (monensin)/LINCOMIX (lincomycin).
095-546	Roxarsone/ROBENZ (robenididine).
102-485	3-NITRO (roxarsone)/AVATEC (lasalocid).
105-758	3-NITRO (roxarsone)/AMPROL HI-E (amprolium and ethopabate)/BACIFERM (bacitracin zinc).
112-661	3-NITRO (roxarsone)/AVATEC (lasalocid)/LINCOMIX (lincomycin).
112-687	3-NITRO (roxarsone)/AVATEC (lasalocid)/FLAVOMYCIN (bambermycins).
116-082	3-NITRO (roxarsone)/AVATEC (lasalocid)/BMD (bacitracin MD).
116-088	3-NITRO (roxarsone)/COBAN (monensin)/BMD (bacitracin MD).
123-154	3-NITRO (roxarsone)/BACIFERM (bacitracin zinc)/COBAN (monensin).
126-052	3-NITRO (roxarsone)/AVATEC (lasalocid)/BACIFERM (bacitracin zinc).
131-894	3-NITRO (roxarsone)/AVATEC (lasalocid)/bacitracin MD.
132-447	Roxarsone/BIO-COX (salinomycin).