

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 510 and 520**

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

**Oral Dosage Form 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 172 approved new

animal drug applications (NADAs) and 14 approved abbreviated new animal drug applications (ANADAs) for oral dosage form new animal drug products from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc. FDA is also amending the animal drug regulations to remove entries describing conditions of use for new animal drug products for which no NADA is approved, to make minor corrections, and to reflect a current format. This is being done to increase the accuracy and readability of the regulations.

**DATES:** This rule is effective May 20, 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](mailto: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 172 approved NADAs and 14 approved ANADAs in table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 as follows:

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

File No.	Product name
006-707 .....	SULQUIN (sulfaquinoxaline) 6-50 Soluble Powder.
006-891 .....	SUL-Q-NO <sub>2</sub> (sulfaquinoxaline) Liquid 34%.
007-879 .....	TERRAMYCIN VET (oxytetracycline hydrochloride) Capsules.
007-981 .....	SOXISOL (sulfisoxazole) Tablets.
008-622 .....	TERRAMYCIN (oxytetracycline hydrochloride) Soluble Powder.
009-339 .....	CARAFEN (ammonium chloride and caramiphen edisylate) Cough Syrup.
009-392 .....	Primidone Tablets.
010-091 .....	MYLEPSIN (primidone) Tablets.
011-060 .....	TERRAMYCIN (oxytetracycline hydrochloride) Scour Tablets.
011-299 .....	PARVEX (piperazine and carbon disulfide) Suspension.
011-315 .....	NEOMIX 325 (neomycin sulfate) Soluble Powder.
011-403 .....	MEDROL (methylprednisolone) Tablets.
011-482 .....	VETAME (triflupromazine hydrochloride) Tablets.
011-582 .....	VETAMOX (acetazolamide sodium) Soluble Powder.
011-590 .....	PARVEX (piperazine and carbon disulfide) Bolus.
011-700 .....	CORTABA (methylprednisolone and acetylsalicylic acid) Tablets.
012-437 .....	TEMARIL-P (trimeprazine tartrate and prednisolone) Tablets.
012-656 .....	Promazine Granules.
012-956 .....	DYREX (trichlorfon) Bolus, Capsules, Granules, Tablets.
013-201 .....	DARBAZINE SPANSULE (prochlorperazine and isopropamide) Capsules.
013-248 .....	Freed No. 10 or 25 (trichlorfon and atropine).
013-957 .....	S.E.Z. (sulfaethoxypyridazine) for Drinking Water 6.25%.
014-366 .....	CYTOBIN (liothyronine sodium) Tablets.
015-102 .....	ALBON (sulfadimethoxine) Tablets.
015-126 .....	Spectinomycin Tablet and Injection.
015-154 .....	DYREX T.F. (trichlorfon, phenothiazine, and piperazine dihydrochloride) Powder.
015-160 .....	Sodium Sulfachloropyrazine Solution.
015-506 .....	WINSTROL-V (stanazolol) Tablets.
030-137 .....	MYLEPSIN (primidone) Tablets.
030-415 .....	FLUCORT (flumethasone) Tablets.
030-416 .....	MESULFIN (sulfamethizole and methenamine mandelate) Tablets.
031-205 .....	AGRIBON (sulfadimethoxine) 12.5% Drinking Water Solution.
031-448 .....	RHEAFORM (iodochlorhydroxyquin) Bolus.
031-553 .....	ESB 3 (sodium sulfachloropyrazine monohydrate) Solution and Soluble Powder.
031-715 .....	ALBON (sulfadimethoxine) Boluses.
031-914 .....	NEO-DARBAZINE SPANSULE (prochlorperazine, isopropamide, and neomycin sulfate) Capsule.
032-738 .....	PACITRAN (metoserpate hydrochloride).
032-946 .....	MAGNA TERRAMYCIN (oxytetracycline hydrochloride and carbomycin) Soluble Powder.
033-149 .....	PARVEX PLUS (piperazine, carbon disulfide, phenothiazine) Suspension.
033-342 .....	PROBAN (cythioate) Tablets 30 mg.
033-606 .....	PROBAN (cythioate) Oral Liquid.
033-653 .....	S.E.Z. (sulfaethoxypyridazine) Drinking Water Solution.
033-654 .....	S.E.Z. (sulfaethoxypyridazine) Oblets 15 G.
033-760 .....	BLOAT GUARD (poloxalene) Drench Concentrate.
033-887 .....	LINCOCIN (lincomycin hydrochloride) Tablets.
035-161 .....	TEMARIL-P SPANSULE (trimeprazine tartrate and prednisolone) Capsules.
035-650 .....	DYREX (trichlorfon and atropine) Powder.
038-160 .....	MAOLATE (chlorphenesin carbamate) Tablets.
039-356 .....	TRAMISOL (levamisole hydrochloride) Cattle Wormer Bolus.

TABLE 1—NADAS AND ANADAS BEING TRANSFERRED FROM PFIZER, INC., TO ZOETIS, INC.—Continued

File No.	Product name
039-357 .....	RIPERCOL L (levamisole hydrochloride) Soluble Drench Powder.
039-729 .....	THERABLOAT (poloxalene) Oral Liquid.
040-587 .....	LINCOCIN (lincomycin hydrochloride) Aquadrops.
041-629 .....	Spectinomycin Oral Liquid.
041-665 .....	TRANVET (propiopromazine hydrochloride) Chewable Tablets.
042-548 .....	AMFOROL (kanamycin sulfate, attapulgite, bismuth subcarbonate) Suspension.
042-740 .....	TRAMISOL (levamisole hydrochloride) Soluble Drench Powder for Sheep.
042-837 .....	TRAMISOL (levamisole hydrochloride) Sheep Wormer Oblerts.
042-841 .....	AMFOROL (kanamycin sulfate, attapulgite, bismuth subcarbonate) Oral Tablets.
042-888 .....	BANMINTH/STRONGID (pyrantel tartrate) Pellets.
043-078 .....	CENTRINE (aminopentamide hydrogen sulfate) Oral Tablets.
043-785 .....	ALBON (sulfadimethoxine) Oral Suspension 5%.
045-513 .....	RIPERCOL L (levamisole hydrochloride) Soluble Powder.
045-515 .....	EQUIBUTE (phenylbutazone) Tablets 100 mg.
045-715 .....	ROBAXIN-V (methocarbamol) Tablets.
046-109 .....	L-S 50 (lincomycin hydrochloride and spectinomycin sulfate) Water Soluble Powder.
046-285 .....	AGRIBON (sulfadimethoxine) Soluble Powder.
047-033 .....	S.E.Z. (sulfaethoxypyridazine) C-R Oblerts 15 Gm.
049-892 .....	SPANBOLET II (sulfamethazine).
055-013 .....	OMNIPEN (ampicillin anhydrous) Capsules 250 mg.
055-020 .....	AUREOMYCIN (chlortetracycline bisulfate) Soluble Powder.
055-032 .....	DICLOXIN (dicloxacillin sodium monohydrate) Capsules.
055-042 .....	AMPI-TAB (ampicillin trihydrate) Tablets.
055-047 .....	CHLOROMYCETIN (chloramphenicol palmitate) Oral Suspension.
055-051 .....	CHLOROMYCETIN (chloramphenicol) Tablets.
055-060 .....	Penicillin G Potassium, USP.
055-073 .....	PANMYCIN (tetracycline hydrochloride) Tablets.
055-074 .....	AMPI-BOL (ampicillin trihydrate) Boluses.
055-076 .....	ALBAPLEX (tetracycline hydrochloride novobiocin sodium) Tablets.
055-078 .....	AMOXI-TABS (amoxicillin trihydrate) Tablets.
055-080 .....	AMOXI-DOSER (amoxicillin trihydrate) Oral Suspension.
055-081 .....	AMOXI-TABS (amoxicillin trihydrate) Tablets.
055-085 .....	AMOXI-DROP (amoxicillin trihydrate) Oral Suspension.
055-087 .....	AMOXI-BOL (amoxicillin trihydrate) Boluses.
055-088 .....	AMOXI-SOL (amoxicillin trihydrate) Soluble Powder.
055-099 .....	CLAVAMOX (amoxicillin trihydrate and clavulanate potassium) Tablets.
055-101 .....	CLAVAMOX (amoxicillin trihydrate and clavulanate potassium) Drops.
065-004 .....	PANMYCIN 500 (tetracycline hydrochloride) Bolus.
065-060 .....	PANMYCIN AQUADROPS (tetracycline hydrochloride) Liquid.
065-061 .....	TETRACHEL-VET (tetracycline hydrochloride) Drops and Syrup.
065-066 .....	TETRACHEL-VET (tetracycline hydrochloride) Tablets 100.
065-069 .....	TETRACHEL-VET (tetracycline hydrochloride) Capsules 500.
065-090 .....	DELTA ALBAPLEX (tetracycline hydrochloride, novobiocin sodium, prednisolone) Tablets.
065-099 .....	ALBAPLEX (tetracycline hydrochloride and novobiocin sodium) Capsules.
065-107 .....	ENTROMYCIN (bacitracin methylene disalicylate and streptomycin sulfate) Soluble Powder.
065-121 .....	Tetracycline-Vet (tetracycline hydrochloride) Capsules 250.
065-123 .....	Tetracycline Soluble Powder.
065-140 .....	TET-SOL 324 (tetracycline hydrochloride) Soluble Powder.
065-241 .....	MYCHEL-VET (chloramphenicol) Capsules (50 mg).
065-270 .....	POLYOTIC (tetracycline hydrochloride) Oblerts.
065-280 .....	FORTRACIN (bacitracin methylene disalicylate) Soluble.
065-313 .....	BACIFERM 50 (bacitracin zinc) Soluble Powder.
065-409 .....	PANMYCIN (tetracycline hydrochloride) Capsules.
065-410 .....	TETRA-SAL (tetracycline hydrochloride).
065-441 .....	POLYOTIC (tetracycline hydrochloride) Soluble Powder.
065-470 .....	BMD (bacitracin methylene disalicylate) 50% Soluble Powder.
065-489 .....	MYCHEL-VET (chloramphenicol) Tablets.
091-065 .....	ROBIZONE-V (phenylbutazone) Tablets 100 mg.
091-327 .....	GASTROGRAFIN (diatrizoate meglumine and diatrizoate sodium) Oral Solution.
091-739 .....	STRONGID T (pyrantel pamoate) Oral Suspension.
092-237 .....	RIPERCOL L-Piperazine (levamisole hydrochloride and piperazine dihydrochloride) Oral Solution.
093-105 .....	ROBIZONE-V (phenylbutazone) Tablets 1 g.
093-107 .....	ALBON S.R. (sulfadimethoxine) Boluses.
093-512 .....	DIROCIDE (diethylcarbamazine citrate) Tablets.
093-688 .....	RIPERCOL L-Piperazine (levamisole hydrochloride and piperazine dihydrochloride) Soluble Powder.
093-903 .....	RUMATEL (morantel tartrate) Cattle Wormer Bolus.
095-333 .....	DIFOLIN (dichlorophene and toluene) Capsules.
095-641 .....	ARQUEL (meclofenamic acid) Granules.
096-509 .....	NBC Kaps Wormer (n-butyl chloride) Capsules.
096-674 .....	EQUIPROXEN (naproxen) Granules.
100-094 .....	Poultry Sulfa (sulfamerazine, sulfamethazine, sulfaquinoxaline) Soluble Powder.
100-237 .....	NEMEX (pyrantel pamoate) Oral Suspension.

TABLE 1—NADAS AND ANADAS BEING TRANSFERRED FROM PFIZER, INC., TO ZOETIS, INC.—Continued

File No.	Product name
100-929 .....	PRIMOR (sulfadimethoxine and ormetoprim) Tablets.
102-709 .....	CHEQUE (mibolerone) Drops.
103-390 .....	TORBUTROL (butorphanol tartrate) Tablets.
104-493 .....	FILARIBITS (diethylcarbamazine) Chewable Tablets.
107-085 .....	TRAMISOL (levamisole hydrochloride) Tablets.
108-687 .....	PET DERM III (dexamethasone) Tablets.
109-722 .....	ANTHELCIDE EQ (oxibendazole) Suspension.
110-048 .....	VALBAZEN (albendazole) Oral Suspension.
110-201 .....	ARQUEL (meclofenamic acid) Tablets.
110-776 .....	BENZELMIN (oxfendazole) Powder For Suspension.
110-777 .....	BENZELMIN (oxfendazole) Top Dress Pellets.
111-636 .....	LINCOMIX (lincomycin hydrochloride) Soluble Powder
115-578 .....	DI-TRIM (trimethoprim and sulfadiazine) Tablets.
120-161 .....	ANTIROBE (clindamycin hydrochloride) Capsules.
121-042 .....	ANTHELCIDE EQ (oxibendazole) Paste.
125-961 .....	RE-SORB Powder for Oral Solution.
126-232 .....	CALFSPAN (sulfamethazine) Tablets.
126-237 .....	TRAMISOL (levamisole hydrochloride) Gel.
128-070 .....	VALBAZEN (albendazole) Oral Paste.
128-517 .....	PET-DEC (diethylcarbamazine citrate) Tablets.
129-831 .....	BANMINTH-P/STRONGID (pyrantel pamoate) Paste.
130-435 .....	OXY-TET (oxytetracycline hydrochloride) Soluble Powder.
131-808 .....	DIROCIDE (diethylcarbamazine citrate) Syrup.
132-105 .....	BENZELMIN (oxfendazole) Equine Anthelmintic Paste.
133-841 .....	BENZELMIN (oxfendazole) Equine Anthelmintic Suspension.
134-779 .....	PARATECT FLEX (morantel Tartrate) Bolus.
135-544 .....	WINSTROL-V (stanazolol) Chewable Tablets.
135-940 .....	ANTIROBE AQUADROPS (clindamycin hydrochloride) Liquid.
136-342 .....	DI-TRIM 400 (trimethoprim and sulfadiazine) Paste.
136-483 .....	FILARIBITS PLUS (diethylcarbamazine citrate and oxbendazole) Chewable Tablets.
136-740 .....	BENZELMIN PLUS (oxfendazole and trichlorfon) Paste.
140-578 .....	SOLU-TET 324 (tetracycline hydrochloride) Soluble Powder.
140-819 .....	STRONGID C and C 2X (pyrantel tartrate) Equine Anthelmintic.
140-892 .....	SYNANTHIC (oxfendazole) Bovine Dewormer Paste 18.5%.
140-893 .....	CESTEX (epsiprantel) Tablets.
140-909 .....	SULKA-S (sulfamethazine) Bolus.
140-934 .....	VALBAZEN (albendazole) Oral Suspension.
141-004 .....	ROBAMOX-V (amoxicillin trihydrate) for Oral Suspension.
141-005 .....	ROBAMOX-V (amoxicillin trihydrate) Tablets.
141-051 .....	PROHEART (moxidectin) Tablets.
141-053 .....	RIMADYL (carprofen) Caplets for Dogs.
141-060 .....	DECCOX-M (decoquinate) Medicated Powder for Whole Milk.
141-080 .....	ANIPRYL (selegiline hydrochloride) Tablets.
141-087 .....	QUEST 2% (moxidectin) Equine Oral Gel.
141-111 .....	RIMADYL (carprofen) Chewable Tablets.
141-151 .....	ZENIQUIN (marbofloxacin) Tablets.
141-216 .....	QUEST PLUS (moxidectin and praziquantel) Gel.
141-232 .....	SIMPICEF (cefpodoxime) Tablets.
141-260 .....	SLENTROL (dirlotapide) Oral Solution.
141-262 .....	CERENIA (maropitant) Tablets.
141-295 .....	PALLADIA (toceranib phosphate) Tablets.
200-046 .....	Neomycin Sulfate Soluble Powder.
200-106 .....	R-PEN (penicillin G potassium) Soluble Powder.
200-113 .....	BIOSOL (neomycin sulfate) Oral Liquid.
200-122 .....	SOLU-PEN (penicillin G potassium) Soluble Powder.
200-130 .....	NEO-SOL 50 (neomycin sulfate) Oral Solution.
200-189 .....	Lincomycin Soluble.
200-233 .....	LINCO Soluble.
200-244 .....	TUCOPRIM (trimethoprim and sulfadiazine) Powder.
200-441 .....	AUREOMYCYN (chlortetracycline) Soluble Powder.

Accordingly, the Agency is amending the regulations in 21 CFR part 520 to reflect these transfers of ownership. Also, 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.

Following this change of sponsorship, Pfizer, Inc., and its wholly owned subsidiaries are no longer sponsors of an approved NADA. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect this change of sponsorship.

In addition, FDA has noticed that certain sections of part 520 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

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 520

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 510 and 520 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. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Alpharma, LLC”; “Fort Dodge Animal Health, Division of Wyeth”; “Fort Dodge Animal Health, Division of Wyeth Holdings Corp.”; “Pfizer, Inc.”; and “Pharmacia & Upjohn Co.”; and in the table in paragraph (c)(2), remove the entries for “000009”, “000069”, “000856”, “046573”, and “053501”.

#### 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. Revise § 520.28 to read as follows:

#### § 520.28 Acetazolamide.

(a) **Specifications.** A powder containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

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

(c) **Conditions of use in dogs—**(1) **Amount.** Administer orally at a dosage of 5 to 15 milligrams per pound of body weight daily.

(2) **Indications for use.** As an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.

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

#### § 520.38a [Amended]

- 5. In paragraph (b) of § 520.38a, remove “000069” and in its place add “054771”.

#### § 520.38b [Amended]

- 6. In paragraph (b) of § 520.38b, remove “000069” and in its place add “054771”.

- 7. Revise § 520.62 to read as follows:

#### § 520.62 Aminopentamide.

(a) **Specifications.** Each tablet contains 0.2 milligram (mg) aminopentamide hydrogen sulphate.

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

(c) **Conditions of use in dogs and cats—**(1) **Amount.** Administer orally every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg; for animals weighing 11 to 20 lbs: 0.2 mg; for animals weighing 21 to 50 lbs: 0.3 mg; for animals weighing 51 to 100 lbs: 0.4 mg; for animal weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(2) **Indications for use.** For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

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

- 8. Revise § 520.82 to read as follows:

#### § 520.82 Aminopropazine oral dosage forms.

- 9. Revise § 520.82a to read as follows:

#### § 520.82a Aminopropazine.

(a) **Specifications.** Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base.

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

(c) **Conditions of use in dogs and cats—**(1) **Amount.** Administer orally at a dosage of 1 to 2 milligrams per pound of body weight, repeated every 12 hours as indicated.

(2) **Indications for use.** For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

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

- 10. Revise § 520.82b to read as follows:

#### § 520.82b Aminopropazine and neomycin.

(a) **Specifications.** Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base and neomycin sulfate equivalent to 50 milligrams (mg) of neomycin base.

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

(c) **Conditions of use in dogs—**(1) **Amount.** Administer orally at a dosage of 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated.

(2) **Indications for use.** For control of bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.

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

- 11. In § 520.88a, revise paragraphs (a), (b), (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

#### § 520.88a Amoxicillin trihydrate film-coated tablets.

(a) **Specifications.** Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams (mg) amoxicillin.

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

(c) \* \* \*

(1) \* \* \*

(i) **Amount.** Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

\* \* \* \* \*

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

(2) \* \* \*

(i) **Amount.** Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

\* \* \* \* \*

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

- 12. In § 520.88b, revise paragraphs (a), (b), (b)(1)(i)(A) and (C), (b)(1)(ii)(A) and (C), and (c)(1)(i) and (iii) to read as follows:

#### § 520.88b Amoxicillin trihydrate for oral suspension.

(a) **Specifications.** When reconstituted, each milliliter contains

amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin.

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

(1) \* \* \*

(i) \* \* \*

(A) *Amount.* Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

\* \* \* \* \*

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

(ii) \* \* \*

(A) *Amount.* Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

\* \* \* \* \*

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

\* \* \* \* \*

(c) \* \* \*

(1) *Conditions of use in dogs—*(i)

*Amount.* Administer orally 5 mg/lb of body weight, twice a day for 5 to 7 days.

\* \* \* \* \*

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

\* \* \* \* \*

■ 13. In § 520.88c, revise paragraphs (a), (b), (d) heading, (d)(1), and (d)(3) to read as follows:

#### **§ 520.88c Amoxicillin trihydrate oral suspension.**

(a) *Specifications.* Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams (mg) amoxicillin.

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

\* \* \* \* \*

(d) *Conditions of use in swine—*(1)

*Amount.* Administer 40 mg orally twice a day using a dosing pump. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days.

\* \* \* \* \*

(3) *Limitations.* Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 14. In § 520.88d, revise paragraphs (a), (b), (d) heading, (d)(1), and (d)(3) to read as follows:

#### **§ 520.88d Amoxicillin trihydrate soluble powder.**

(a) *Specifications.* Each gram of powder contains amoxicillin trihydrate equivalent to 115.4 milligrams (mg) amoxicillin.

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

\* \* \* \* \*

(d) *Conditions of use in preruminating calves including veal calves—*(1)

*Amount.* Administer 400 mg per 100 pounds of body weight twice daily by drench or in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

\* \* \* \* \*

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 15. In § 520.88e, revise paragraphs (a), (b), (d) heading, (d)(1), and (3) to read as follows:

#### **§ 520.88e Amoxicillin trihydrate boluses.**

(a) *Specifications.* Each bolus contains amoxicillin trihydrate equivalent to 400 milligrams (mg) amoxicillin.

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

\* \* \* \* \*

(d) *Conditions of use in cattle—*(1)

*Amount.* Administer 400 mg per 100 pounds of body weight twice daily. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

\* \* \* \* \*

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 16. Revise § 520.88f to read as follows:

#### **§ 520.88f Amoxicillin trihydrate tablets.**

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams (mg) amoxicillin.

(b) *Sponsors.* See Nos. 051311 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1)

*Amount.* Administer 5 mg per pound of body weight twice daily for 5 to 7 days or 48 hours after all symptoms have subsided.

(2) *Indications for use.* For treatment of bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *Escherichia coli*; and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *Proteus mirabilis*, and *Staphylococcus* spp.

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

■ 17. In § 520.88g, revise paragraphs (b), (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

#### **§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.**

\* \* \* \* \*

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

(c) \* \* \*

(1) \* \* \*

(i) *Amount.* 6.25 milligrams

(equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

\* \* \* \* \*

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

(2) \* \* \*

(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

\* \* \* \* \*

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

■ 18. In § 520.88h, revise paragraphs (b), (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

#### **§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.**

\* \* \* \* \*

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

(c) \* \* \*

(1) \* \* \*

(i) *Amount.* 6.25 milligrams

(equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

\* \* \* \* \*

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

(2) \* \* \*

(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily. Administer 48 hours after all signs have subsided. Maximum duration of treatment should not exceed 30 days.

\* \* \* \* \*

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

**§ 520.90a [Reserved]**

- 19. Remove and reserve § 520.90a.
- 20. In § 520.90b, revise the section heading, paragraph (b), paragraph (c) heading, and paragraph (c)(3) to read as follows:

**§ 520.90b Ampicillin tablets.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs—*

\* \* \* \* \*

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

- 21. In § 520.90c, revise the section heading, paragraphs (b), (c)(1)(iii), and (c)(2)(iii) to read as follows:

**§ 520.90c Ampicillin capsules.**

\* \* \* \* \*

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

(c) \* \* \*

(1) \* \* \*

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

(2) \* \* \*

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

- 22. In § 520.90d, revise the section heading, paragraphs (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

**§ 520.90d Ampicillin for oral suspension.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(i) *Amount.* Administer to 10 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. In severe or acute conditions, 10 milligrams per pound of body weight 3 times daily. Duration of treatment is usually 3 to 5 days.

Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided.

\* \* \* \* \*

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

(2) \* \* \*

(i) *Amount.* Administer 10 to 30 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided.

\* \* \* \* \*

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

- 23. In § 520.90e, revise the section heading and paragraph (d)(3) to read as follows:

**§ 520.90e Ampicillin for soluble powder.**

\* \* \* \* \*

(d) \* \* \*

(3) *Limitations.* Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 24. In § 520.90f, revise the section heading and revise paragraph (b) and in paragraphs (d)(1)(ii) and (d)(2)(ii), remove the second sentence..

The revisions read as follows:

**§ 520.90f Ampicillin boluses.**

\* \* \* \* \*

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

- (1) No. 055529 for use as in paragraph (d)(1) of this section;
- (2) No. 054771 for use as in paragraph (d)(2) of this section.

\* \* \* \* \*

- 25. In § 520.110, revise paragraph (d) to read as follows:

**§ 520.110 Apramycin sulfate soluble powder.**

\* \* \* \* \*

(d) *Conditions of use in swine—*(1) *Amount.* Administer in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day for 7 days.

(2) *Indications for use.* For the control of porcine colibacillosis (weanling pig scours) caused by strains of *Escherichia coli* sensitive to apramycin.

(3) *Limitations.* Prepare fresh medicated water daily. Do not slaughter treated swine for 28 days following treatment.

**§ 520.154a [Amended]**

- 26. In paragraph (b) of § 520.154a, remove “046573” and in its place add “054771”.

**§ 520.154b [Amended]**

- 27. In paragraph (b) of § 520.154b, remove “046573” and in its place add “054771”.

**§ 520.154c [Amended]**

- 28. In paragraph (b) of § 520.154c, remove “053501” and in its place add “054771”.

- 29. Revise § 520.246 to read as follows:

**§ 520.246 Butorphanol tablets.**

- (a) *Specifications.* Each tablet contains butorphanol tartrate equivalent

to 1, 5, or 10 milligrams (mg) butorphanol base.

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

(c) *Conditions of use in dogs—*(1)

*Amount.* Administer 0.25 mg butorphanol base per pound of body weight. Repeat at intervals of 6 to 12 hours as required. Treatment should not normally be required for longer than 7 days.

(2) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheobronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

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

**§ 520.260 [Amended]**

- 30. In § 520.260, remove footnote 1 wherever it occurs; and in paragraph (b)(2), remove “000069” and in its place add “054771”.

- 31. In § 520.300a, revise paragraph (c) to read as follows:

**§ 520.300a Cambendazole suspension.**

\* \* \* \* \*

(c) *Conditions of use in horses—*(1) *Amount.* Administer by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(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.

- 32. In § 520.300b, revise paragraph (c) to read as follows:

**§ 520.300b Cambendazole pellets.**

\* \* \* \* \*

(c) *Conditions of use in horses—*(1)

*Amount.* Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

■ 33. In § 520.300c, revise paragraph (c) to read as follows:

**§ 520.300c Cambendazole paste.**

\* \* \* \* \*

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 milligrams cambendazole per kilogram body weight (5 grams per 550 pounds (250 kilograms)) by depositing the paste on the back of the tongue using a dosing gun. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

**§ 520.309 [Amended]**

■ 34. In § 520.309, in paragraph (b)(1), remove “000069” and in its place add “054771”.

**§ 520.310 [Amended]**

■ 35. In § 520.310, in paragraph (b), remove “000856” and in its place add “054771”; and remove footnote 1 wherever it occurs.

**§ 520.370 [Amended]**

■ 36. In § 520.370, in paragraph (b), remove “000009 and 026637” and in its place add “026637 and 054771”.

**§ 520.390a [Amended]**

■ 37. In § 520.390a, in paragraph (b)(1)(ii), remove “000856” and in its

place add “054771”; and remove paragraph (b)(1)(iii).

**§ 520.390b [Amended]**

■ 38. In § 520.390b, in paragraph (b), remove “000069 and 050057” and in its place add “050057 and 054771”.

**§ 520.390c [Amended]**

■ 39. In § 520.390c, in paragraph (b), remove “000856” and in its place add “054771”.

**§ 520.420 [Amended]**

■ 40. In § 520.420, remove footnote 1 wherever it occurs.

**§ 520.434 [Amended]**

■ 41. In § 520.434, in paragraph (b), remove “000009” and in its place add “054771”; and in paragraph (c)(3), remove the first four sentences.

**§ 520.441 [Amended]**

■ 42. In § 520.441, in paragraph (b)(2), remove “046573 and 000010” and in its place add “000010 and 054771”.

**§ 520.446 [Amended]**

■ 43. In § 520.446, in paragraph (b)(1), remove “000009 and 000859” and in its place add “000859 and 054771”.

**§ 520.447 [Amended]**

■ 44. In § 520.447, in paragraph (b), remove “000009, 000859, 051311” and in its place add “000859, 051311, 054771”.

**§ 520.530 [Amended]**

■ 45. In § 520.530, in paragraph (b), remove “053501” and in its place add “054771”; and in paragraph (d)(3), remove the first two sentences.

■ 46. Amend § 520.531 as follows:

- a. Add paragraph (a);
- b. Remove paragraph (c);
- c. Redesignate paragraph (d) as paragraph (c); and
- d. Revise paragraph (b) and newly redesignated paragraph (c)(3).

The addition and revision read as follows:

**§ 520.531 Cythioate tablets.**

(a) *Specifications.* Each tablet contains 30 or 90 milligrams (mg) cythioate.

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

(1) No. 000859 for use of 30- and 90-mg tablets;

(2) No. 054771 for use of the 30-mg tablet.

(c) \* \* \*

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

■ 47. In § 520.534, revise paragraph (a), and in paragraph (b), remove “046573” and in its place add “054771”. The revision reads as follows:

**§ 520.534 Decoquinate.**

(a) *Specifications.* Each gram of powder contains 8 milligrams (0.8 percent) decoquinate.

\* \* \* \* \*

■ 48. Revise § 520.540a to read as follows:

**§ 520.540a Dexamethasone powder.**

(a) *Specifications.* Each packet contains 10 milligrams (mg) of dexamethasone.

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

(c) *Conditions of use in cattle and horses*—(1) *Amount.* Administer 5 to 10 mg per animal the first day then 5 mg per day as required by drench or by sprinkling on a small amount of feed.

(2) *Indications for use.* As supportive therapy following parenteral steroid administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

■ 49. In § 520.540b, remove footnote 1 wherever it occurs; and revise paragraphs (a)(3) and (b)(3) to read as follows:

**§ 520.540b Dexamethasone tablets and boluses.**

(a) \* \* \*

(3) *Conditions of use in cattle and horses*—(i) *Amount.* Administer orally 5 to 10 milligrams on the first day, then 5 milligrams per day as required.

(ii) *Indications for use.* As supportive therapy following parenteral steroid administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(b) \* \* \*

(3) *Conditions of use in dogs and cats*—(i) *Amount*. Dogs: Administer orally 0.25 to 1.25 milligrams per day for up to 7 days. Cats: Administer orally 0.125 to 0.5 milligrams per day for up to 7 days.

(ii) *Indications for use*. As an anti-inflammatory agent.

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

- 50. Amend § 520.540c as follows:
- a. Remove footnote 1 wherever it occurs;
- b. In paragraph (b), remove “000069” and in its place add “054771”; and
- c. Revise paragraph (c).

The revision reads as follows:

**§ 520.540c Dexamethasone chewable tablets.**

\* \* \* \* \*

(c) *Conditions of use in dogs*—(1) *Amount*. Administer by free-choice feeding or crumbled over food 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.

(2) *Indications for use*. As supportive therapy in nonspecific dermatosis and inflammatory conditions.

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

**§ 520.550 [Removed]**

- 51. Remove § 520.550.
- 52. In § 520.563, revise the section heading, remove “053501” in paragraph (b) and in its place add “054771”, and revise paragraph (c).

The revisions read as follows:

**§ 520.563 Dexamethasone chewable tablets.**

\* \* \* \* \*

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer orally 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. Administered rectally 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(2) *Indications for use*. For radiography of the gastrointestinal tract.

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

**§ 520.580 [Amended]**

- 53. In § 520.580, in paragraph (b)(2), remove “054628” and in its place add “054771”.
- 54. In § 520.608, revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 520.608 Dicloxacillin.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally 5 to 10 milligrams per pound of body weight, three times daily. In severe cases, up to 25 milligrams per pound of body weight three times daily.

(2) *Indications for use*. For the treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to dicloxacillin.

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

**§ 520.622a [Amended]**

- 55. In § 520.622a, in paragraph (a)(2), remove “053501” and in its place add “054771”.

**§ 520.622b [Amended]**

- 56. In § 520.622b, in paragraph (a)(2), remove “053501” and in its place add “054771”.

**§ 520.622c [Amended]**

- 57. In § 520.622c, in paragraph (b)(2), remove “000069” and in its place add “054771”.
- 58. In § 520.623, revise the section heading and paragraphs (b) and (c)(3) to read as follows:

**§ 520.623 Diethylcarbamazine and oxibendazole chewable tablets.**

\* \* \* \* \*

(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.

**§ 520.666 [Amended]**

- 59. In § 520.666, in paragraph (b), remove “000069” and in its place add “054771”.
- 60. Revise § 520.763 to read as follows:

**§ 520.763 Dithiazanine oral dosage forms.**

- 61. Revise § 520.763a to read as follows:

**§ 520.763a Dithiazanine tablets.**

(a) *Specifications*. Each tablet contains 10, 50, 100, or 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor*. See No. 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount*.

Administer orally immediately after feeding as follows:

(i) For large roundworms (*Toxocara canis*, *Toxascaris leonina*): 10 mg per

pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For *Strongyloides* (*Strongyloides canis*, *Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitis*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

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

- 62. Revise § 520.763b to read as follows:

**§ 520.763b Dithiazanine powder.**

(a) *Specifications*. Each tablespoon of powder contains 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount*.

Administer orally by mixing in food as follows:

(i) For large roundworms (*Toxocara canis*, *Toxascaris leonina*): 10 mg per pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For *Strongyloides* (*Strongyloides canis*, *Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitis*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

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

- 63. In § 520.763c, redesignate paragraph (d) as paragraph (c); and revise paragraphs (a), (b), and the redesignated paragraph (c) heading to read as follows:

**§ 520.763c Dithiazanine and piperazine suspension.**

(a) *Specifications*. Each milliliter of suspension contains 69 milligrams (mg) dithiazanine iodide and 83 mg piperazine base (as piperazine citrate).

(b) *Sponsor*. See No. 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—

\* \* \* \* \*

■ 64. Amend § 520.784 by revising the section heading and paragraph (c) to read as follows:

**§ 520.784 Doxylamine.**

\* \* \* \* \*

(c) *Conditions of use*—(1) *Amount*.

Horses: Administer orally 1 to 2 milligrams (mg) per pound (/lb) of body weight per day divided into 3 or 4 equal doses. Dogs and cats: Administer orally 2 to 3 mg/lb of body weight per day divided into 3 or 4 equal doses.

(2) *Indications for use*. For use when antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(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.

■ 65. Revise § 520.804 to read as follows:

**§ 520.804 Enalapril.**

(a) *Specifications*. Each tablet contains 1.0, 2.5, 5.0, 10, or 20 milligrams (mg) of enalapril maleate.

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

(c) *Conditions of use in dogs*—(i) *Amount*. Administer orally 0.5 to 1.0 mg of enalapril maleate per kilogram of body weight per day.

(ii) *Indications for use*. For the treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

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

■ 66. In § 520.816, revise the section heading and paragraphs (b) and (c)(3) to read as follows:

**§ 520.816 Epsiprantel.**

\* \* \* \* \*

(b) *Sponsor*. See No. 050604 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.

■ 67. In § 520.823, revise the section heading and paragraph (a) to read as follows:

**§ 520.823 Erythromycin.**

(a) *Specifications*. Each gram of powder contains erythromycin phosphate equivalent to 0.89 gram of erythromycin master standard.

\* \* \* \* \*

■ 68. Amend § 520.863 as follows:

■ a. Revise the section heading;

■ b. Remove footnote 1 wherever it occurs; and

■ c. Revise paragraph (c).  
The revisions read as follows:

**§ 520.863 Ethylisobutrazine.**

\* \* \* \* \*

(c) *Conditions of use in dogs*—(1) *Amount*.

Administer orally 2 to 5 milligrams per pound of body weight once daily.

(2) *Indications for use*. As a tranquilizer.

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

■ 69. In § 520.870, add paragraph (c) and remove paragraph (d).

The addition reads as follows:

**§ 520.870 Etodolac.**

\* \* \* \* \*

(c) *Conditions of use in dogs*—(1) *Amount*.

Administer 10 to 15 mg per kilogram (4.5 to 6.8 mg per pound) of body weight per day orally.

(2) *Indications for use*. For the management of pain and inflammation associated with osteoarthritis.

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

■ 70. Revise § 520.903a to read as follows:

**§ 520.903a Febantel paste.**

(a) *Specifications*. Each gram of paste contains 455 milligrams (45.5 percent) febantel.

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

(c) *Conditions of use in horses*—(1) *Amount*.

Administer paste orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use*. For removal of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); ascarids (*Parascaris equorum*—sexually mature and immature); pinworms (*Oxyuris equi*—adult and 4th stage larva); and various small strongyles in horses, foals, and ponies.

(3) *Limitations*. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

■ 71. In § 520.903b, revise paragraphs (a), (b), and (c) to read as follows:

**§ 520.903b Febantel suspension.**

(a) *Specifications*. Each ounce of suspension contains 2.75 grams (9.3 percent ounce) febantel.

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

(c) *Conditions of use in horses*—(1) *Amount*. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight). Administer by stomach tube or drench, or by mixing well into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use*. For removal of ascarids (*Parascaris equorum*—adult and sexually immature), pinworms (*Oxyuris equi*—adult and 4th stage larvae), large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*), and various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

(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.

\* \* \* \* \*

■ 72. In § 520.903d, revise the section heading and paragraph (c)(3) and remove paragraph (c)(4).

The revisions read as follows:

**§ 520.903d Febantel and praziquantel paste.**

\* \* \* \* \*

(c) \* \* \*

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

■ 73. In § 520.903e, revise paragraphs (b) and (c)(3) to read as follows:

**§ 520.903e Febantel tablets.**

\* \* \* \* \*

(b) *Sponsor*. 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.

■ 74. In § 520.960, revise the section heading and paragraphs (b) and (c)(3) to read as follows:

**§ 520.960 Flumethasone.**

\* \* \* \* \*

(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.

■ 75. Add § 520.1060 to read as follows:

**§ 520.1060 Glucose and glycine.**

(a) *Specifications*. Each packet of powder contains 8.82 grams sodium chloride, 4.20 grams potassium

phosphate, 0.5 gram citric acid anhydrous, 0.12 gram potassium citrate, 6.36 grams aminoacetic acid (glycine), and 44.0 grams glucose.

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

(c) *Conditions of use in calves*—(1) *Amount.* Dissolve each packet in 2 quarts of warm water and administer to each calf as follows:

(i) *Scouring and/or dehydrated calves.* Feed 2 quarts of solution, twice daily for 2 days (four feedings). No milk or milk replacer should be fed during this period. For the next four feedings (days 3 and 4), use 1 quart of solution together with 1 quart of milk replacer. Thereafter, feed as normal.

(ii) *Newly purchased calves.* Feed 2 quarts of solution instead of milk as the first feed upon arrival. For the next scheduled feeding, use 1 quart of solution mixed together with 1 quart of milk or milk replacer. Thereafter, feed as normal.

(2) *Indications for use.* For control of dehydration associated with diarrhea (scours); and as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(3) *Limitations.* The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. A veterinarian should be consulted in severely scouring calves. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

■ 76. In § 520.1100, revise paragraphs (d)(1)(ii) and (d)(2)(i)(A) to read as follows:

#### § 520.1100 Griseofulvin.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) \* \* \*

(i) \* \* \*

(A) Daily (single or divided) dose as follows: For animals weighing up to 6 pounds: 62.5 milligrams; for animals weighing 6 to 18 pounds: 125 milligrams; for animals weighing 18 to 36 pounds: 250 milligrams; for animals weighing 36 to 48 pounds: 375 milligrams; for animal weighing 48 to 75 pounds: 500 milligrams.

\* \* \* \* \*

■ 77. Amend § 520.1120a as follows:

■ a. Remove paragraph (a);

■ b. Redesignate paragraphs (b) through (f) as paragraphs (a) through (e), respectively; and  
 ■ c. Revise newly redesignated paragraphs (a) and (e).

The revisions read as follows:

#### § 520.1120a Haloxon drench.

\* \* \* \* \*

(a) *Specifications.* Each packet contains 141.5 grams haloxon.

\* \* \* \* \*

(e) *Conditions of use in cattle*—(1)

*Amount.* Dissolve each packet in 32 fluid ounces of water and administer as follows: For animals weighing up to 100 pounds: 1/2 fluid ounce; for animals weighing 100 to 150 pounds: 3/4 fluid ounce; for animals weighing 150 to 200 pounds: 1 fluid ounce; for animals weighing 200 to 300 pounds: 1 1/2 fluid ounces; for animals weighing 300 to 450 pounds: 2 fluid ounces; for animals weighing 450 to 700 pounds: 3 fluid ounces; for animals weighing 700 to 1,000 pounds: 4 fluid ounces; for animals weighing 1,000 to 1,200 pounds: 5 fluid ounces; for animals weighing over 1,200 pounds: 6 fluid ounces. Retreat in 3 to 4 weeks.

(2) *Indications for use.* For control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations.* Do not treat dairy animals of breeding age. Do not treat within 1 week of slaughter.

■ 78. Amend § 520.1120b as follows:  
 ■ a. Remove paragraph (a);  
 ■ b. Redesignate paragraphs (b) through (e) as paragraphs (a) through (d), respectively; and  
 ■ c. Revise newly redesignated paragraph (d).

The revisions read as follows:

#### § 520.1120b Haloxon boluses.

\* \* \* \* \*

(d) *Conditions of use in cattle*—(1)

*Amount.* Administered one bolus per 500 pounds body weight (35 to 50 milligrams per kilogram of body weight). Retreat in 3 to 4 weeks.

(2) *Indications for use.* For control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations.* Do not treat dairy animals of breeding age or older. Do not treat within 1 week of slaughter.

■ 79. In § 520.1157, revise the section heading and paragraph (c)(3) to read as follows:

#### § 520.1157 Iodinated casein.

\* \* \* \* \*

(c) \* \* \*

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

■ 80. In § 520.1158, revise the section heading and paragraphs (b) and (c)(3) to read as follows:

#### § 520.1158 Iodochlorhydroxyquin.

\* \* \* \* \*

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

(c) \* \* \*

(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.

■ 81. In § 520.1196, revise the section heading and paragraphs (c)(1)(i) and (iii) to read as follows:

#### § 520.1196 Ivermectin and pyrantel tablets.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(i) *Amount.* Administer a minimum of 6 µg of ivermectin and 5 mg of pyrantel per kilogram (2.72 µg and 2.27 mg per pound) of body weight monthly.

\* \* \* \* \*

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

\* \* \* \* \*

#### § 520.1199 [Amended]

■ 82. In § 520.1199, in paragraph (b), remove “*Sponsors*” and in its place add “*Sponsor*”.

#### § 520.1204 [Amended]

■ 83. In § 520.1204, in paragraph (b), remove “000856” and in its place add “054771”.

■ 85. Revise § 520.1242b to read as follows:

#### § 520.1242b Levamisole boluses or oblets.

(a) *Specifications.* Each bolus contains 2.19 grams levamisole hydrochloride. Each oblet contains 0.184 grams levamisole hydrochloride.

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

(c) *Required labeling.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Related tolerances.* See § 556.350 of this chapter.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer orally 2.19-gram boluses as a single dose as follows: 250 to 450 pounds, 1/2 bolus; 450 to 750 pounds, 1 bolus; and 750 to 1,050 pounds, 1 1/2 boluses.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Consult veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* Administer orally one 0.184-gram oblet for each 50 pounds of body weight.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult a veterinarian before using in severely debilitated animals.

■ 86. Revise § 520.1242c to read as follows:

#### § 520.1242c Levamisol and piperazine.

(a) *Specifications.* (1) Each ounce of solution contains 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) A soluble powder which when constituted with water contains in each fluid ounce 0.45 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 5.0 grams of piperazine base.

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

(c) *Conditions of use in horses*—(1) *Amount.* Aqueous solution: administer by stomach tube or drench 1 fluid ounce per 100 pounds of body weight. Reconstituted soluble powder: administer by stomach tube 1 fluid ounce per 125 pounds of body weight. If reinfection occurs, re-treat animals at 6- to 8-week intervals.

(2) *Indications for use.* An anthelmintic effective against infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*), small strongyles (*Cylicocercus* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp., *Cylicotrapedon*

spp.), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equi*).

(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.

#### § 520.1242e [Amended]

■ 87. In paragraph (b) of § 520.1242e, remove “053501” and in its place add “054771”.

■ 88. In § 520.1242f, revise the section heading and paragraphs (a) and (b) to read as follows:

#### § 520.1242f Levamisol gel.

(a) *Specifications.* Each gram of gel contains 115 milligrams (11.5 percent) levamisole hydrochloride.

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

\* \* \* \* \*

■ 89. Amend § 520.1242g as follows:

- a. Remove paragraph (a);
- b. Redesignate paragraphs (b) through (f) as paragraphs (a) through (e); and
- c. Revise newly redesignated paragraph (d).

The revision reads as follows:

#### § 520.1242g Levamisole resinate and tamphur paste.

\* \* \* \* \*

(d) *Related tolerances.* See §§ 556.273 and 556.350 of this chapter.

\* \* \* \* \*

■ 90. Revise § 520.1263a to read as follows:

#### § 520.1263a Lincomycin tablets and syrup.

(a) *Specifications.* (1) Each ounce of syrup contains lincomycin hydrochloride equivalent to either 25 or 50 milligrams (mg) lincomycin.

(2) Each tablet contains lincomycin hydrochloride equivalent to either 25 or 50 mg lincomycin.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 10 mg per pound of body weight every 12 hours, or 7 mg per pound of body weight every 8 hours, for up to 12 days.

(2) *Indications for use.* For infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

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

#### § 520.1263c [Amended]

■ 91. In § 520.1263c, in paragraph (b)(1) remove “000009” and in its place add “054771”; and in paragraph (b)(2)

remove “046573” and in its place add “054771”.

#### § 520.1265 [Amended]

■ 92. In § 520.1265, in paragraph (b)(1) remove “000009” and in its place add “054771”.

■ 93. Revise § 520.1284 to read as follows:

#### § 520.1284 Liothyronine.

(a) *Specifications.* Each tablet contains 60 or 120 micrograms (μg) liothyronine as the sodium salt.

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

(c) *Conditions of use in dogs*—(1)

*Amount.* Administer orally to dogs at levels up to 12.8 μg per kilogram (/kg) of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8 μg/kg of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(2) *Indications for use.* For treatment of hypothyroidism in dogs.

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

■ 94. In § 520.1310, in paragraph (b), remove “000069” and in its place add “054771”; and revise the section heading to read as follows:

#### § 520.1310 Marbofloxacin.

\* \* \* \* \*

#### § 520.1315 [Amended]

■ 95. In paragraph (b) of § 520.1315, remove “000069” and in its place add “054771”.

■ 96. Revise § 520.1320 to read as follows:

#### § 520.1320 Mebendazole.

(a) *Specifications.* (1) Each gram of powder contains either 40 or 166.7 milligrams of mebendazole.

(2) Each gram of paste contains 200 milligrams of mebendazole.

(3) Each milliliter of suspension contains 33.3 milligrams of mebendazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use.* For treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small

strongyles; and mature and immature (4th larval stage) pinworms (*Oxyuris equi*).

(iii) *Limitations.* The drug is compatible with carbon disulfide. 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.

(2) *Dogs—(i) Amount.* Administer 100 milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder by mixing with a small quantity of food, preferably before the regular meal.

(ii) *Indications for use.* The drug is used for treatment of infections of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

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

■ 97. In § 520.1326a revise the paragraph (c) heading and paragraph (c)(3) to read as follows:

**§ 520.1326a Mebendazole and trichlorfon powder.**

\* \* \* \* \*

(c) *Conditions of use in horses—*

\* \* \* \* \*

(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.

■ 98. In § 520.1326b revise the paragraph (c) heading to read as follows:

**§ 520.1326b Mebendazole and trichlorfon paste.**

\* \* \* \* \*

(c) *Conditions of use in horses—*

\* \* \* \* \*

■ 99. Revise § 520.1330 to read as follows:

**§ 520.1330 Meclofenamic acid granules.**

(a) *Specifications.* Each gram of granules contains 5 milligrams (5 percent) meclofenamic acid.

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

(c) *Conditions of use in horses—(1) Amount.* Administer 1 milligram per pound of body weight (1 gram per 1000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(2) *Indications for use.* For the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(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.

■ 100. In § 520.1331 revise paragraphs (b) and (c)(3) to read as follows:

**§ 520.1331 Meclofenamic acid tablets.**

\* \* \* \* \*

(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.

■ 101. In § 520.1341, revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 520.1341 Megestrol.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs—(1) Amount.* Administer orally, intact, or crushed and mixed with food as follows:

(i) For the postponement of estrus by proestrus treatment: 1 milligram per pound of body weight per day for 8 days.

(ii) For the postponement of estrus by anestrus treatment: 0.25 milligram per pound of body weight per day for 32 days.

(iii) For alleviation of false pregnancy: 1 milligram per pound of body weight per day for 8 days.

(2) *Indications for use.* For the postponement of estrus and the alleviation of false pregnancy in female dogs.

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

■ 102. Revise § 520.1380 to read as follows:

**§ 520.1380 Methocarbamol.**

(a) *Specifications.* Each tablet contains 500 milligrams (mg) of methocarbamol.

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

(c) *Conditions of use in dogs and cats—(1) Amount.* Administer 60 mg per pound of body weight in two or three equally divided doses, followed each following day by 30 to 60 mg per pound of body weight, usually not to exceed 14 to 21 days.

(2) *Indications for use.* As an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

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

■ 103. Revise § 520.1408 to read as follows:

**§ 520.1408 Methylprednisolone.**

(a) *Specifications.* Each tablet contains 1, 2, or 4 milligrams (mg) of methylprednisolone.

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

(1) No. 054628 for use of 1- and 2-mg tablets.

(2) No. 054771 for use of 1- and 4-mg tablets.

(c) *Conditions of use in dogs and cats—(1) Amount.* 5 to 15 pounds (lbs): 2 mg; 15 to 40 lbs: 2 to 4 mg; 40 to 80 lbs: 4 to 8 mg. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed.

(2) *Indications for use.* As an anti-inflammatory agent.

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

■ 104. Amend § 520.1409 as follows:

■ a. Revise the section heading and paragraph (b);

■ b. Remove paragraphs (c) and (d);

■ c. Redesignate paragraph (e) as paragraph (c); and

■ d. Revise newly redesignated paragraph (c).

The revisions read as follows:

**§ 520.1409 Methylprednisolone and aspirin.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs—(1) Amount.* Under 15 pounds,  $\frac{1}{4}$  to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily. Administer total daily dose in divided doses 6 to 10 hours apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* As an anti-inflammatory and analgesic agent.

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

**§ 520.1422 [Amended]**

■ 105. In § 520.1422, in paragraph (b), remove “053501” and in its place add “054771”.

■ 106. In § 520.1430 revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 520.1430 Megestrol acetate tablets.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs—(1) Amount.* 30 micrograms for animals

weighing 1 to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, German Shepherds, or German Shepherd mix. Administer daily, orally or in a small amount of food, at least 30 days before expected initiation of heat, and continue daily as long as desired, but not for more than 24 months.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

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

#### § 520.1450a [Amended]

■ 107. In § 520.1450a, in paragraph (b), remove “000069” and in its place add “054771”.

#### § 520.1450b [Amended]

■ 108. In § 520.1450b, in paragraph (b), remove “000069” and in its place add “054771”.

#### § 520.1450c [Amended]

■ 109. In § 520.1450c, in paragraph (b), remove “000069” and in its place add “054771”.

#### § 520.1451 [Amended]

■ 110. In § 520.1451, in paragraph (b), remove “000856” and in its place add “054771”; remove paragraph (c); redesignate paragraph (d) as paragraph (c); and in newly redesignated paragraph (c)(3), remove the first sentence.

■ 111. In § 520.1452, in paragraph (b), remove “000856” and in its place add “054771”; and revise paragraph (d)(3) to read as follows:

#### § 520.1452 Moxidectin gel.

\* \* \* \* \*

(d) \* \* \*

(3) *Limitations.* Do not use in horses intended for human consumption.

■ 112. In § 520.1453, in paragraph (b), remove “000856” and in its place add “054771”; and revise paragraph (d)(3) to read as follows:

#### § 520.1453 Moxidectin and praziquantel gel.

\* \* \* \* \*

(d) \* \* \*

(3) *Limitations.* Do not use in horses intended for human consumption.

■ 113. Revise § 520.1468 to read as follows:

#### § 520.1468 Naproxen.

(a) *Specifications.* Each gram of granules contains 500 milligrams (mg) (50 percent) naproxen.

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

(c) *Conditions of use in horses—(1) Amount.* 10 mg per kilogram of body weight twice daily top dressed on feed for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system.

(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.

#### § 520.1484 [Amended]

■ 114. In § 520.1484, in paragraph (b)(1) remove “000069” and in its place add “054771”; in paragraph (b)(2) remove “000009, 046573,” and in its place add “054771;” and in paragraph (b)(3) remove “000009, 000859,” and in its place add “000859, 054771.”

#### § 520.1628 [Amended]

■ 115. In paragraph (b) of § 520.1628, remove “000856” and in its place add “054771”.

#### § 520.1629 [Amended]

■ 116. In § 520.1629, in paragraphs (a)(2) and (b)(2), remove “000856” and in its place add “054771”.

■ 117. Revise paragraph (b) of § 520.1630 to read as follows:

#### § 520.1630 Oxfendazole suspension.

\* \* \* \* \*

(b) *Sponsor.* See Nos. 000010 and 054771 in § 510.600(c) of this chapter.

\* \* \* \* \*

#### § 520.1631 [Amended]

■ 118. In § 520.1631, in paragraph (b), remove “000856” and in its place add “054771”.

■ 119. Revise § 520.1638 to read as follows:

#### § 520.1638 Oxbendazole.

(a) *Specifications—(1) Each gram of paste contains 227 milligrams (mg) (22.7 percent) oxbendazole.*

(2) Each milliliter of suspension contains 100 mg (10 percent) oxbendazole.

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

(c) *Special considerations—(1) See § 500.25 of this chapter.*

(2) Suspension product described in paragraph (a)(2) of this section shall be

labeled: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) *Conditions of use in horses—(1) Amount.* For uses other than for threadworms (*Strongyloides westeri*), 10 mg oxbendazole per kilogram (/kg) body weight; for threadworms (*Strongyloides westeri*), 15 mg/kg. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Administer suspension product by stomach tube in 3 to 4 pints of warm water, or by top dressing or mixing into a portion of the normal grain ration.

(2) *Indications for use.* For removal and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small strongyles (genera *Cylicostephanus*, *Cylicocyclus*, *Cyathostomum*, *Triodontophorus*, *Cylicodontophorus*, and *Gyalocephalus*); large roundworms (*Parascaris equorum*); pinworms (*Oxyuris equi*) including various larval stages; and threadworms (*Strongyloides westeri*).

(3) *Limitations.* Do not use in horses intended for human consumption.

#### § 520.1640 [Removed]

■ 120. Remove § 520.1640.

#### § 520.1660a [Amended]

■ 121. In paragraph (b) of § 520.1660a, remove “000069” and in its place add “054771”.

#### § 520.1660b [Amended]

■ 122. In § 520.1660b, in paragraph (b), remove “000069” and in its place add “054771”; and in paragraph (c), wherever it occurs, remove footnote 1.

#### § 520.1660c [Amended]

■ 123. In § 520.1660c, in paragraphs (b) and (d)(3), remove “000069” and in its place add “No. 054771”.

#### § 520.1660d [Amended]

■ 124. In § 520.1660d, in paragraphs (b)(1), (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove “000069” and in its place add “054771”; in paragraph (b)(2), remove “046573” and in its place add “054771”; in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove “046573, 053389” and in its place add “048164, 054771”; and in paragraph (d)(1)(ii)(C)(3), in the seventh sentence, remove “salughter” and in its place add “slaughter”.

#### § 520.1696b [Amended]

■ 125. In § 520.1696b, in paragraph (b), remove “046573, 053501” and in its place add “054771”.

- 126. Amend § 520.1696c as follows:
  - a. Remove paragraph (c);
  - b. Redesignate paragraph (d) as paragraph (c); and
  - c. Revise newly redesignated paragraph (c) heading and (c)(3).

The revisions read as follows:

**§ 520.1696c Penicillin V powder.**

\* \* \* \* \*

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

\* \* \* \* \*

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

- 127. Amend § 520.1696d as follows:
  - a. Revise paragraph (b);
  - b. Remove paragraph (c);
  - c. Redesignate paragraph (d) as paragraph (c);
  - d. Revise newly redesignated paragraph (c) heading and (c)(3).

The revisions read as follows:

**§ 520.1696d Penicillin V tablets.**

\* \* \* \* \*

(b) *Sponsors*. See Nos. 050604 and 054771 in § 510.600(c) of this chapter.

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

\* \* \* \* \*

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

**§ 520.1720a [Amended]**

- 128. In § 520.1720a, in paragraph (b)(3), remove “000856” and in its place add “054771”.
- 129. Revise § 520.1720b to read as follows:

**§ 520.1720b Phenylbutazone granules.**

(a) *Specifications*. Each package of granules contains 1 or 8 grams of phenylbutazone.

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

(1) No. 000061 for 8-gram package.

(2) No. 059320 for 1-gram package.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily as required, by adding to a portion of the usual grain ration.

(2) *Indications for use*. For the treatment of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 130. In § 520.1720c, revise paragraph (c)(3) to read as follows:

**§ 520.1720c Phenylbutazone paste.**

\* \* \* \* \*

(c) \* \* \*

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 131. Amend § 520.1720d as follows:
  - a. Remove paragraph (c);
  - b. Redesignate paragraph (d) as paragraph (c); and
  - c. Revise newly redesignated paragraph (c)(3).

The revisions read as follows:

**§ 520.1720d Phenylbutazone gel.**

\* \* \* \* \*

(c) \* \* \*

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 132. Amend § 520.1802a as follows:
  - a. In paragraph (b), remove “000009” and in its place add “No. 054771”;
  - b. Remove footnote 1 wherever it appears in paragraph (c); and
  - c. Revise the paragraph (c) heading and paragraphs (c)(1) and (3)

The revisions read as follows:

**§ 520.1802a Piperazine-carbon disulfide complex suspension.**

\* \* \* \* \*

(c) *Conditions of use in horses and ponies*—(1) *Amount*. Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

\* \* \* \* \*

(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.

- 133. Amend § 520.1802b as follows:
  - a. In paragraph (b), remove “000009” and in its place add “No. 054771”;
  - b. Revise the paragraph (c) heading; and
  - c. Remove footnote 1 wherever it appears in paragraph (c).

The revision reads as follows:

**§ 520.1802b Piperazine-carbon disulfide complex boluses.**

\* \* \* \* \*

(c) *Conditions of use in horses and ponies*—

\* \* \* \* \*

- 134. In § 520.1802c, in paragraph (b), remove “000009” and in its place add

“No. 054771”; and revise the paragraph (c) heading and paragraphs (c)(1) and (3) to read as follows:

**§ 520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.**

\* \* \* \* \*

(c) *Conditions of use in horses and ponies*—(1) *Amount*. Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

\* \* \* \* \*

(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.

- 135. In § 520.1803, revise paragraphs (a) and (c) to read as follows:

**§ 520.1803 Piperazine citrate capsules.**

(a) *Specifications*. Each capsule contains piperazine citrate equivalent to 140 milligrams of piperazine base.

\* \* \* \* \*

(c) *Conditions of use in dogs and cats*—(1) *Amount*. The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in 1/2 of the regular feeding and when the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfestation may occur. Repeat treatment if indicated.

(2) *Indications for use*. For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(3) *Limitations*. Severely debilitated animals should not be treated except on the advice of a veterinarian.

**§ 520.1804 [Amended]**

- 136. In § 520.1804, in paragraph (b), remove “051311” and in its place add “054771”; and in paragraph (c) remove footnote 1 wherever it appears.

- 137. In § 520.1805, revise paragraph (c)(3) to read as follows:

**§ 520.1805 Piperazine phosphate and thenium closylate tablets.**

\* \* \* \* \*

(c) \* \* \*

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

**§ 520.1807 [Amended]**

- 138. In § 520.1807, in paragraph (b), remove “015565” and in its place add “No. 015565”.

**§ 520.1840 [Amended]**

- 139. In § 520.1840, in paragraph (b)(1), remove “000069” and in its place add “054771”.
- 140. In § 520.1855, revise paragraph (c)(3) to read as follows:

**§ 520.1855 Ponazuril.**

\* \* \* \* \*

(c) \* \* \*

(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.

- 141. Amend § 520.1860 as follows:
- a. Remove paragraph (c);
- b. Redesignate paragraph (d) as paragraph (c); and

- c. Add paragraph (c)(3).

The addition reads as follows:

**§ 520.1860 Pradofloxacin.**

\* \* \* \* \*

(c) \* \* \*

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

- 142. Amend § 520.1880 as follows:

- a. Revise the section heading;
- b. Remove paragraph (c);
- c Redesignate paragraph (d) as paragraph (c); and
- d. Revise the newly redesignated paragraph (c) heading and paragraphs (c)(1) and (2).

The revisions read as follows:

**§ 520.1880 Prednisolone.**

\* \* \* \* \*

(c) *Conditions of use in dogs—(1)*

*Amount.* Administer 2.5 milligrams per 4.5 kilograms (10 pounds) body weight per day. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* For use as an anti-inflammatory agent.

\* \* \* \* \*

- 143. In § 520.1900, revise the section heading and paragraphs (b) and (c)(3) to read as follows:

**§ 520.1900 Primidone.**

\* \* \* \* \*

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

(1) No. 054628 for use of 250 milligram tablets.

(2) No. 054771 for use of 50 and 250 milligram tablets.

(c) \* \* \*

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

- 144. Revise § 520.1920 to read as follows:

**§ 520.1920 Prochlorperazine and isopropamide.**

(a) *Specifications.* Each capsules contains either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide); or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

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

(c) *Conditions of use in dogs—(1)*

*Amount.* (i) Capsules described in paragraph (a)(1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a)(2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(2) *Indications for use.* For the treatment of gastrointestinal disturbances associated with emotional stress.

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

- 145. In § 520.1921, revise the section heading, paragraph (b), the paragraph (c) heading, and paragraphs (c)(2) and (3) to read as follows:

**§ 520.1921 Prochlorperazine, isopropamide, and neomycin.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs—*

\* \* \* \* \*

(2) *Indications for use.* For the treatment infectious bacterial gastroenteritis associated with emotional stress.

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

- 146. Revise § 520.1962 to read as follows:

**§ 520.1962 Promazine.**

(a) *Specifications.* Conforms to N.F. XII for promazine hydrochloride.

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

(c) *Conditions of use in horses—(1)*

*Amount.* Administer 0.45 to 0.9 milligrams per pound of body weight mixed with an amount of feed that will be readily consumed.

(2) *Indications for use.* For quieting excitable, unruly, or intractable horses.

(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.

- 147. Revise § 520.2002 to read as follows:

**§ 520.2002 Propiopromazine.**

(a) *Specifications.* Each chewable tablet contains 10 or 20 milligrams of propiopromazine hydrochloride.

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

(c) *Conditions of use in dogs—(1)*

*Amount.* Administer 0.5 to 2.0 milligrams per pound of body weight once or twice daily, depending upon the degree of tranquilization desired.

(2) *Indications for use.* For oral administration as a tranquilizer. As an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking, car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

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

**§ 520.2043 [Amended]**

- 148. In § 520.2043, in paragraph (b)(1), remove “000069, 000859” and in its place add “000859, 054771”; and in paragraph (b)(2), remove “000069” and in its place add “054771”.

**§ 520.2044 [Amended]**

- 149. In § 520.2044, in paragraph (b)(1), remove “000069” and in its place add “054771”.

- 150. Revise § 520.2045 to read as follows:

**§ 520.2045 Pyrantel tartrate powder.**

(a) *Specifications.* Each gram of powder contains 106 milligrams (10.6 percent) or 113 milligrams (11.3 percent) pyrantel tartrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of 11.3 percent powder as in paragraph (d)(1) and 10.6 percent powder as in paragraph (d)(2) and of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Conditions of use—(1) Horses—(i) Amount.* Administer as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration. Do not administer by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(iii) *Limitations.* Do not treat severely debilitated animals with this drug. Do not use in horses intended for human consumption.

(2) *Swine—(i) Amount.* Add to feed at 0.4 gram pyrantel tartrate per pound of non-pelleted ration. The ration is administered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(ii) *Indications for use.* For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(iii) *Limitations.* Consult veterinarian before using in severely debilitated animals. Do not treat within 24 hours of slaughter.

■ 151. Add § 520.2046 to read as follows:

#### § 520.2046 Pyrantel tartrate pellets.

(a) *Specifications.* (1) Each gram of pellets contains 12.5 milligrams (mg) (1.25 percent) pyrantel tartrate; or

(2) Each gram of pellets contains 21.1 mg (2.11 percent) pyrantel tartrate.

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

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

(2) No. 061623 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(c) *Conditions of use in horses—(1) Amount.* Administer as a single dose at 12.5 mg per 2.2 pounds of body weight mixed with the usual grain ration.

(2) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(3) *Limitations.* Do not treat severely debilitated animals with this drug. Do

not use in horses intended for human consumption.

■ 152. Revise § 520.2098 to read as follows:

#### § 520.2098 Selegiline.

(a) *Specifications.* Each tablet contains 2, 5, 10, 15, or 30 milligrams (mg) selegiline hydrochloride.

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

(c) *Conditions of use in dogs—(1) Amounts and indications for use.* (i) Administer 1 mg per kilogram (0.45 mg per pound) of body weight once daily for control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) Administer 0.5 to 1.0 mg per kilogram of body weight once daily for the control of clinical signs associated with canine cognitive dysfunction syndrome.

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

■ 153. Revise § 520.2100 to read as follows:

#### § 520.2100 Selenium and vitamin E.

(a) *Specifications.* Each capsule contains:

(1) 2.19 milligrams (mg) sodium selenite (equivalent to 1 mg selenium) and 56.2 mg (68 I.U.) vitamin E as d-alpha tocopheryl acid succinate; or

(2) 0.548 mg sodium selenite (equivalent to 0.25 mg selenium) and 14 mg (17 I.U.) vitamin E as d-alpha tocopheryl acid succinate.

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

(c) *Conditions of use in dogs—(1) Amount.* (i) Dogs over 20 pounds: Administer 1 capsule described in paragraph (a)(1) per 20 pounds of body weight to a maximum of 5 capsules. Repeat at 3 day intervals until a satisfactory therapeutic response is observed. Maintenance dosage is 1 capsule per 40 pounds of body weight every 3 to 7 days, or longer, as required.

(ii) Dogs under 20 pounds: Administer 1 capsule described in paragraph (a)(2) per 5 pounds of body weight with a minimum of 1 capsule. Repeat at 3-day intervals until a satisfactory response is observed. Maintenance dosage is 1 capsule per 10 pounds of body weight every 3 to 7 days, or longer, as required.

(2) *Indications for use.* As an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies.

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

■ 154. In § 520.2123a, revise paragraphs (a) and (b) to read as follows:

#### § 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 054771 and 061623 in § 510.600(c) of this chapter.

\* \* \* \* \*

#### § 520.2123c [Amended]

■ 155. In § 520.2123c, in paragraph (b), remove “0000856, 000859, and 061623” and in its place add “000859, 054771, and 061623”.

■ 156. Revise § 520.2150 to read as follows:

#### § 520.2150 Stanazolol.

(a) *Specifications.* Each tablet or chewable tablet contains 2 milligrams stanozolol.

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

(c) *Conditions of use in dogs and cats—(1) Amount—(i) Dogs:*

Administered orally to small breeds,  $\frac{1}{2}$  to 1 tablet twice daily for several weeks; to large breeds, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

(ii) *Cats:* Administered orally  $\frac{1}{2}$  to 1 tablet twice daily for several weeks.

(2) *Indications for use.* As an anabolic steroid treatment.

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

#### § 520.2150a [Removed]

■ 157. Remove § 520.2150a.

#### § 520.2150b [Removed]

■ 158. Remove § 520.2150b.

#### § 520.2158 [Removed]

■ 159. Remove § 520.2158.

#### § 520.2158a as [Redesignated as § 520.2158]

■ 160–161. Redesignate § 520.2158a as § 520.2158 and revise the section heading and paragraph (a) to read as follows:

#### § 520.2158 Streptomycin.

(a) *Specifications.* Each milliliter of solution contains 250 milligrams (25 percent) streptomycin sulfate.

\* \* \* \* \*

#### § 520.2158b [Removed]

■ 162. Remove § 520.2158b.

#### § 520.2158c [Removed]

■ 163. Remove § 520.2158c.

**§ 520.2160 [Removed]**

- 164. Remove § 520.2160.
- 165. Amend § 520.2170 as follows:
  - a. Revise the section heading;
  - b. Remove paragraph (d);
  - c. Redesignate paragraphs (b), (c), and (e) as paragraphs (c), (b), and (d), respectively; and
  - d. Revise newly redesignated paragraph (d) heading and paragraphs (d)(1) and (3).

The revisions read as follows:

**§ 520.2170 Sulfabromomethazine.**

\* \* \* \* \*

- (d) *Conditions of use in cattle*—(1) *Amount*. Administer 90 milligrams per pound body weight orally. Repeat in 48 hours if necessary

\* \* \* \* \*

(3) *Limitations*. Milk taken from animals within 96 hours (8 milkings) of latest treatment must not be used for food. Do not administer within 18 days of slaughter.

- 166. Revise § 520.2184 to read as follows:

**§ 520.2184 Sulfachloropyrazine.**

(a) *Specifications*. Each gram of powder contains 476 milligrams of sodium sulfachloropyrazine monohydrate.

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

(c) *Related tolerance*. See § 556.625 of this chapter.

(d) *Conditions of use in chickens*. It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:

(1) *Amount*. Administer in drinking water as 0.03 percent solution for 3 days.

(2) *Indications for use*. For the treatment of coccidiosis.

(3) *Limitations*. Administer as sole source of drinking water and of sulfonamide medication. Withdraw 4 days prior to slaughter. Do not use in chickens producing eggs for human consumption.

- 167. In § 520.2200, revise paragraph (d)(3)(iii) to read as follows:

**§ 520.2200 Sulfachlorpyridazine.**

\* \* \* \* \*

(d) \* \* \*

(3) \* \* \*

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

**§ 520.2218 [Amended]**

- 168. In § 520.2218, in paragraph (b), remove “046573” and in its place add “054771”.

- 169. Revise § 520.2220a to read as follows:

**§ 520.2220a Sulfadimethoxine solution and soluble powder.**

(a) *Specifications*. (1) Each ounce of solution contains 3.75 grams (12.5 percent) sulfadimethoxine.

(2) Each 107 grams of powder contains the equivalent of 94.6 grams sulfadimethoxine as sulfadimethoxine sodium.

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

(1) Nos. 000859, 054628, 054771, 054925, and 057561 for use of the product described in paragraph (a)(1) of this section.

(2) Nos. 054771, 054925, 057561, 058829, 061623, and 066104 for use of the product described in paragraph (a)(2) of this section.

(c) *Related tolerances*. See § 556.640 of this chapter.

(d) *Conditions of use*—(1) *Broiler and replacement chickens*—(i) *Amount*.

Administer 1.875 grams per gallon (0.05 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use*. For treatment of outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) *Limitations*. Do not administer to chickens over 16 weeks of age. As sole source of drinking water and sulfonamide medication. Withdraw 5 days before slaughter.

(2) *Turkeys*—(i) *Amount*. Administer 0.938 grams per gallon (0.025 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use*. Growing turkeys: For treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations*. Do not administer to turkeys over 24 weeks of age. Use as the sole source of drinking water and sulfonamide medication. Withdraw 5 days before slaughter.

(3) *Cattle*—(i) *Amount*. 1.18 to 2.36 grams per gallon (0.031 to 0.062 percent) of drinking water. As a drench, administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days. If no improvement within 2 to 3 days, reevaluate diagnosis. Do not treat beyond 5 days.

(ii) *Indications for use*. Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

(iii) *Limitations*. Withdraw 7 days before slaughter. A withdrawal period

has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

- 170. Revise § 520.2220b to read as follows:

**§ 520.2220b Sulfadimethoxine suspension.**

(a) *Specifications*. Each milliliter of suspension contains 50 milligrams (mg) sulfadimethoxine.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily.

(2) *Indications for use*. For the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

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

- 171. Revise § 520.2220c to read as follows:

**§ 520.2220c Sulfadimethoxine tablet.**

(a) *Specifications*. Each tablet contains 125, 250, or 500 milligrams (mg) sulfadimethoxine.

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

(c) [Reserved]

(d) *Conditions of use in dogs and cats*—(1) *Amount*. Administer 25 milligrams (mg) per pound of body weight on the first day followed by 12.5 milligrams (mg) per pound of body weight per day until the animal is free of symptoms for 48 hours.

(2) *Indications for use*. Treatment of sulfadimethoxine-susceptible bacterial infections.

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

- 172. Revise § 520.2220d to read as follows:

**§ 520.2220d Sulfadimethoxine bolus.**

(a) *Specifications*. Each bolus contains 2.5, 5, or 15 grams sulfadimethoxine.

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

(c) *Related tolerances*. See § 556.640 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.

(2) *Indications for use*. For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to

sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations.* Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 173. Add § 520.2220e to read as follows:

**§ 520.2220e Sulfadimethoxine extended-release bolus.**

(a) *Specifications.* Each extended-release bolus contains 12.5 grams sulfadimethoxine.

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

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use in beef cattle and non-lactating dairy cattle—(1) Amount.* Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.

(2) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 174. Add § 520.2220f to read as follows:

**§ 520.2220f Sulfadimethoxine and ormetoprim tablet.**

(a) *Specifications.* Each tablet contains 120 milligrams (mg) (100 mg sulfadimethoxine and 20 mg ormetoprim), 240 mg (200 mg sulfadimethoxine and 40 mg ormetoprim), 600 mg (500 mg sulfadimethoxine and 100 mg ormetoprim), or 1200 mg (1000 mg sulfadimethoxine and 200 mg ormetoprim).

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

(c) *Conditions of use in dogs—(1) Amount.* On the first day of treatment, administer 25 mg per pound (55 mg per kilogram) of body weight. Then follow with a daily dosage of 12.5 mg per pound (27.5 mg per kilogram) of body

weight. Do not exceed a total of 21 consecutive days.

(2) *Indications of use.* Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *E. coli*, *Staphylococcus* spp., and *Proteus mirabilis* susceptible to ormetoprim-potentiated sulfadimethoxine.

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

■ 175. Revise § 520.2240a to read as follows:

**§ 520.2240a Sulfaethoxypyridazine solution.**

(a) *Specifications.* Each milliliter of solution contains 62.5 milligrams (mg) sodium sulfaethoxypyridazine.

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

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use—(1) Swine—(i) Amount.* Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Do not treat within 10 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle—(i) Amount.* For use at 2.5 grams per gallon. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; and as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 176. Revise § 520.2240b to read as follows:

**§ 520.2240b Sulfaethoxypyridazine tablets.**

(a) *Specifications—(1) Each tablet contains 2.5 or 15 grams sulfaethoxypyridazine.*

(2) Each extended-release tablet contains 5 grams sulfaethoxypyridazine.

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

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use in cattle—(1) 2.5- or 15-gram tablets—(i) Amount.* Administer 25 milligrams per pound of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *15-gram extended-release tablets—(i) Amount.* Administer 100 milligrams per pound of body weight. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (*E. coli*, *Streptococci*, *Staphylococci*, *Sphaerophorus necrophorus* and Gram-negative rods including *Pasteurella*); and for use prophylactically during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Not for use in lactating dairy cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**§ 520.2260a [Amended]**

■ 177. In § 520.2260a, in paragraph (b)(1), remove “053501” and in its place add “054771”.

■ 178. Amend § 520.2260b as follows:

■ a. In paragraph (b)(1), remove “053501” and in its place add “054771”;

■ b. In paragraph (c)(2), remove footnote 1 wherever it occurs; and

■ c. In paragraph (c)(2)(iii), remove the eighth sentence and in its place add two sentences.

The additions read as follows:

**§ 520.2260b Sulfamethazine extended-release boluses.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(iii) \* \* \* Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. \* \* \*

\* \* \* \* \*

■ 179. Amend § 520.2260c as follows:

■ a. Redesignate paragraphs (a) and (b) as paragraphs (b) and (d), respectively;

- b. Add new paragraphs (a) and (c); and
- c. Revise newly redesignated paragraphs (b) and (d)(3).

The additions and revisions read as follows:

**§ 520.2260c Sulfamethazine extended-release tablets.**

(a) *Specifications.* Each extended-release tablet contains 8 grams sulfamethazine.

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

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) \* \* \*

(3) *Limitations.* Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 180. Amend § 520.2261a as follows:
  - a. Remove paragraph (d);
  - b. Redesignate paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively;
  - c. Add new paragraph (a);
  - d. Revise newly redesignated paragraphs (b) and (c); and
  - e. In newly redesignated paragraph (d)(2)(iii), remove “*Salmonella pullorum*” and in its place add “*Salmonella Pullorum*”.

The addition and revisions read as follows:

**§ 520.2261a Sulfamethazine solution.**

(a) *Specifications.* Each milliliter of solution contains 125 milligrams (12.5 percent) sulfamethazine sodium.

(b) *Sponsors.* See Nos. 000010 and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

\* \* \* \* \*

- 181. In § 520.2261b, revise paragraph (d)(1)(ii) and add four sentences to paragraph (d)(4)(iii) to read as follows:

**§ 520.2261b Sulfamethazine powder.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) *Indications for use.* For control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *E. necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella Pullorum*).

\* \* \* \* \*

(4) \* \* \*

(iii) \* \* \* Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

- 182. In § 520.2280, revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 520.2280 Sulfamethizole and methenamine.**

\* \* \* \* \*

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

(c) *Conditions of use in dogs and cats—(1) Amount.* Administer orally 1 tablet per 20 pounds of body weight 3 times per day until clinical signs are alleviated. To reduce the possibility of relapse, continue therapy for a week to 10 days.

(2) *Indications for use.* For treatment of urinary tract infections such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. As an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

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

- 183. In § 520.2325a, revise the section heading and in paragraph (a)(3), remove “046573” and in its place add “054771”.

The revision reads as follows:

**§ 520.2325a Sulfaquinoxaline powder and solution.**

\* \* \* \* \*

- 184. Revise § 520.2325b to read as follows:

**§ 520.2325b Sulfaquinoxaline drench.**

(a) *Specifications.* A soluble powder containing 25 percent sulfaquinoxaline.

(b) *Sponsor.* See No. 050749 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle—(1)*

*Amount.* Administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(2) *Indications for use.* For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zuernii*.

(3) *Limitations.* Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

**§ 520.2330 [Amended]**

- 185. In paragraph (b) of § 520.2330, remove “000856” and in its place add “054771”; and in paragraph (c), remove footnote 1 wherever it occurs.

- 186. In § 520.2345a, revise the section heading and paragraph (b) to read as follows:

**§ 520.2345a Tetracycline capsules.**

\* \* \* \* \*

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

\* \* \* \* \*

- 187. In § 520.2345b, revise paragraph (b) to read as follows:

**§ 520.2345b Tetracycline tablets.**

\* \* \* \* \*

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

\* \* \* \* \*

- 188. In § 520.2345c, revise paragraph (b) to read as follows:

**§ 520.2345c Tetracycline boluses.**

\* \* \* \* \*

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

\* \* \* \* \*

- 189. Amend § 520.2345d as follows;
- a. In paragraph (b)(1), remove “000069” and in its place add “054771”;

- b. In paragraphs (b)(3), (d)(1)(iii), and (d)(2)(iii), remove “046573” and in its place add “054771”; and

- c. Add paragraph (b)(5).

The addition reads as follows:

**§ 520.2345d Tetracycline powder.**

\* \* \* \* \*

(b) \* \* \*

(5) No. 000010: 25 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

\* \* \* \* \*

- 190. In § 520.2345e, revise the section heading and paragraph (b) and remove paragraph (c)(1)(iv).

The revisions read as follows:

**§ 520.2345e Tetracycline solution.**

\* \* \* \* \*

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

\* \* \* \* \*

- 191. In § 520.2345f, in paragraph (b), remove “No. 000009” and in its place add “See No. 054771”; and revise the paragraph (c) heading and paragraph (c)(3) to read as follows:

**§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.**

\* \* \* \* \*

(c) *Conditions of use in dogs—*

\* \* \* \* \*

- 192. In § 520.2345g, in paragraph (b), remove “No. 000009” and in its place add “See No. 054771”; and revise the paragraph (c) heading and paragraph (c)(3) to read as follows:

**§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.**

\* \* \* \* \*

(c) *Conditions of use in dogs*—

\* \* \* \* \*

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

■ 193. In § 520.2345h, in paragraph (b), remove “000009” and in its place add “054771”; and revise the paragraph (c) heading and paragraph (c)(3) to read as follows:

**§ 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.**

\* \* \* \* \*

(c) *Conditions of use in dogs*—

\* \* \* \* \*

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

■ 194. Amend § 520.2362 as follows:

- a. Revise the section heading;
- b. Remove paragraph (a);
- c. Redesignate paragraphs (b), (c), and (d) as paragraphs (a), (b), and (c), respectively; and
- d. Revise newly redesignated paragraphs (a) and (c).

The revisions read as follows:

**§ 520.2362 Thenium closylate.**

(a) *Specifications*. Each tablet contains thenium closylate equivalent to 500 milligrams thenium base.

\* \* \* \* \*

(c) *Conditions of use in dogs*—(1)

*Amount*. Dogs weighing over 10 pounds: Administer 1 tablet as a single dose. Dogs weighing 5 to 10 pounds: Administered one-half tablet twice during a single day. Repeat treatment after 2 or 3 weeks.

(2) *Indications for use*. For treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms).

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

■ 195. Amend § 520.2380a as follows:

- a. Remove paragraph (a);
- b. Redesignate paragraphs (b) through (e) as paragraphs (a) through (d), respectively; and
- c. Revise newly redesignated paragraph (b).

The revision reads as follows:

**§ 520.2380a Thiabendazole top dressing and mineral protein block.**

\* \* \* \* \*

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

(1) No. 051311 for use as in paragraph (d)(1)(i) of this section.

(2) No. 050604 for use as in paragraph (d)(1)(ii) of this section.

(3) No. 012286 for use as in paragraph (d)(2) of this section.

\* \* \* \* \*

■ 196. Amend § 520.2380b as follows:

- a. Revise the section heading;
- b. Remove paragraph (a);
- c. Redesignate paragraphs (b) through (e) as paragraphs (a) through (d), respectively; and
- d. Revise newly redesignated paragraph (b).

The revisions read as follows:

**§ 520.2380b Thiabendazole drench or paste.**

\* \* \* \* \*

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

\* \* \* \* \*

**§ 520.2380c [Amended]**

■ 197. In § 520.2380c, remove paragraph (a); and redesignate paragraphs (b) through (e) as paragraphs (a) through (d), respectively.

■ 198. In § 520.2380d, revise the section heading and paragraph (c) to read as follows:

**§ 520.2380d Thiabendazole and piperazine citrate.**

\* \* \* \* \*

(c) *Conditions of use in horses*—(1)

*Amount*. Administer 1 ounce of suspension per 100 pounds of body weight by stomach tube or as a drench.

(2) *Indications for use*. For the control of large strongyles, small strongyles, pinworms, *Strongyloides* and ascarids (including members of the genera *Strongylos* spp., *Cyathostomum* spp., *Cylicobrachytus* spp. and related genera *Craterostomum* spp., *Oesophagodontus* spp., *Poteriostomum* spp., *Oxyuris* spp., *Strongyloides* spp., and *Parascaris* spp.).

(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.

■ 199. In § 520.2380e, revise the section heading and paragraph (c) to read as follows:

**§ 520.2380e Thiabendazole and trichlorfon.**

\* \* \* \* \*

(c) *Conditions of use in horses*—(1)

*Amount*. Administer 2 grams of thiabendazole with 1.8 grams of trichlorfon per 100 pounds of body weight sprinkled on the animals’ usual daily ration of feed, or may be mixed in 5 to 10 fluid ounces of water and administered by stomach tube or drench.

(2) *Indications for use*. For the treatment and control of bots

(*Gasterophilus* spp.), large strongyles (*Strongylos* spp.), small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*), pinworms (*Oxyuris* spp., *Strongyloides* spp.), and ascarids (*Parascaris* spp.).

(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.

■ 200. In § 520.2380f, revise the section heading, the paragraph (c) heading, and paragraphs (c)(1) and (3) to read as follows:

**§ 520.2380f Thiabendazole and piperazine phosphate.**

\* \* \* \* \*

(c) *Conditions of use in horses*—(1)

*Amount*. 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight. Use a single oral dose. Administer as a drench or by stomach tube suspended in 1 pint of warm water; by dose syringe suspended in 1/2 ounce of water for each 100 pounds of body weight; or sprinkled over a small amount of daily feed.

\* \* \* \* \*

(3) *Limitations*. Do not use in horses intended for human consumption. If the label bears directions for administration by stomach tube or drench, it shall also bear the statement “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”; if not labeled for use by stomach tube or drench, the label shall bear the statement, “Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.”

**§ 520.2475 [Amended]**

■ 201. In § 520.2475, in paragraph (b), remove “000009” and in its place add “054771”.

**§ 520.2520b [Redesignated as § 520.2520a]**

■ 202. Redesignate § 520.2520b as § 520.2520a; and revise it to read as follows:

**§ 520.2520a Trichlorfon and atropine.**

(a) *Specifications*. (1) For trichlorfon: O,O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

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

(c) *Conditions of use in mice*—(1)

*Amount*. Administer 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter continuously for 7 to 14 days as the sole source of drinking water.

(2) *Indications for use.* For the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.

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

**§ 520.2520e [Redesignated as § 520.2520b]**

- 203a. Redesignate § 520.2520e as § 520.2520b.
- 203b. Amend newly redesignated § 520.2520b as follows:
  - a. Revise paragraph (b);
  - b. Remove paragraphs (c) and (d);
  - c. Redesignate paragraph (e) as paragraph (c); and
  - d. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

The revisions read as follows:

**§ 520.2520b Trichlorfon boluses.**

- \* \* \* \* \*
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Conditions of use in horses—*
  - \* \* \* \* \*

(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.

**§ 520.2520f [Redesignated as § 520.2520c]**

- 204a. Redesignate § 520.2520f as § 520.2520c.
- 204b. Amend newly redesignated § 520.2520c as follows:
  - a. Revise paragraph (b);
  - b. Remove paragraphs (c) and (d);
  - c. Redesignate paragraph (e) as paragraph (c); and
  - d. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

The revisions read as follows:

**§ 520.2520c Trichlorfon granules.**

- \* \* \* \* \*
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Conditions of use in horses—*
  - \* \* \* \* \*

(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.

**§ 520.2520g [Redesignated as § 520.2520d]**

- 205a. Redesignate § 520.2520g as § 520.2520d.
- 205b. Amend newly redesignated § 520.2520d as follows:
  - a. Revise paragraph (b);
  - b. Remove paragraphs (c) and (d);
  - c. Redesignate paragraph (e) as paragraph (c); and

■ d. Revise the newly redesigned paragraph (c) heading and paragraph (c)(3).

The revisions read as follows:

**§ 520.2520d Trichlorfon, phenothiazine, and piperazine.**

- \* \* \* \* \*
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Conditions of use in horses—*
  - \* \* \* \* \*

(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.

- 206. Revise § 520.2582 to read as follows:

**§ 520.2582 Triflupromazine.**

- (a) *Specifications.* Each tablet contains 10 or 25 milligrams (mg) triflupromazine hydrochloride.
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Conditions of use in dogs and cats—*
  - (1) *Amount.* Administer orally 1 to 2 mg per pound of body weight daily, followed by 1 mg daily.

(2) *Indications for use.* For relief of anxiety, to help control psychomotor over-activity, and to increase the tolerance of animals to pain and pruritus. For use in various clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

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

- 207. Revise § 520.2604 to read as follows:

**§ 520.2604 Trimeprazine and prednisolone tablets.**

- (a) *Specifications.* Each tablet contains 5 milligrams (mg) trimeprazine tartrate and 2 mg prednisolone.
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Conditions of use in dogs—*
  - (1) *Amount.* Administer orally an initial dosage: for dogs weighing up to 10 pounds, ½ tablet twice daily; for dogs weighing 11 to 20 pounds, 1 tablet twice daily; for dogs weighing 21 to 40 pounds, 2 tablets twice daily; and for dogs weighing over 40 pounds, 3 tablets twice daily. After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms.

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

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

- 208. Revise § 520.2605 to read as follows:

**§ 520.2605 Trimeprazine and prednisolone capsules.**

- (a) *Specifications.* Each capsule contains:

(1) 3.75 milligrams (mg) trimeprazine in sustained released form (as trimeprazine tartrate) and 1 mg prednisolone (Capsule No. 1); or

(2) 7.5 mg trimeprazine in sustained release form (as trimeprazine tartrate) and 2 mg prednisolone (Capsule No. 2).

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

(c) *Conditions of use in dogs—*

- (1) *Amount.* Administer orally once daily an initial dosage:

(i) For dogs weighing up to 10 pounds: one Capsule No. 1;

(ii) For dogs weighing 11 to 20 pounds, one Capsule No. 2 or two Capsule No. 1;

(iii) For dogs weighing 21 to 40 pounds, two Capsule No. 2 or four Capsule No. 1; and

(iv) For dogs weighing over 40 pounds, three Capsule No. 2 or six Capsule No. 1.

After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms.

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

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

- 209. Revise § 520.2610 to read as follows:

**§ 520.2610 Trimethoprim and sulfadiazine tablets.**

- (a) *Specifications.* Each tablet contains 30 milligrams (mg) (5 mg

trimethoprim and 25 mg sulfadiazine), 120 mg (20 mg trimethoprim and 100 mg sulfadiazine), 480 mg (80 mg trimethoprim and 400 mg sulfadiazine) or 960 mg (160 mg trimethoprim and 800 mg sulfadiazine).

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

(c) *Conditions of use in dogs—(1) Amount.* Administer orally at 30 mg per kilogram of body weight (14 milligrams per pound) once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(2) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

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

#### **§ 520.2611 [Amended]**

■ 210. In § 520.2611, in paragraph (b)(1), remove “000856” and in its place add “054771”.

■ 211. In § 520.2613, revise paragraphs (a) and (b), the paragraph (c) heading,

and paragraphs (c)(1) and (3) to read as follows:

#### **§ 520.2613 Trimeprazine and sulfadiazine powder.**

(a) *Specifications.* Each gram of powder contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors.* See Nos. 054771 and 058711 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer orally 3.75 grams of powder per 110 pounds (50 kilograms) of body weight in a small amount of feed, as a single daily dose, for 5 to 7 days.

\* \* \* \* \*

(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.

Dated: April 29, 2014.

**Steven D. Vaughn,**

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

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## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

#### **33 CFR Parts 100 and 165**

**[Docket No. USCG-2013-0904]**

#### **Special Local Regulations and Safety Zones; Recurring Events in Northern New England**

**AGENCY:** Coast Guard, DHS.

**TABLE 1**

[33 CFR 100.120]

### **JUNE**

Charlie Begin Memorial Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Boothbay Harbor Lobster Boat Race Committee.</li> <li>• Date: June 14, 2014.</li> <li>• Time: 10:00 a.m. to 2:00 p.m.</li> <li>• Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of John's Island within the following points (NAD 83):           <ul style="list-style-type: none"> <li>43°50'04" N, 069°38'37" W.</li> <li>43°50'54" N, 069°38'06" W.</li> <li>43°50'49" N, 069°37'50" W.</li> <li>43°50'00" N, 069°38'20" W.</li> </ul> </li> </ul>
Rockland Harbor Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Rockland Harbor Lobster Boat Race Committee.</li> <li>• Date: June 15, 2014.</li> <li>• Time: 10:00 a.m. to 3:00 p.m.</li> <li>• Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of the Rockland Breakwater Light within the following points (NAD 83):           <ul style="list-style-type: none"> <li>44°05'59" N, 069°04'53" W.</li> <li>44°06'43" N, 069°05'25" W.</li> <li>44°06'50" N, 069°05'05" W.</li> </ul> </li> </ul>