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of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

520.23 Acepromazine maleate tablets.
520.44 Acetazolamide sodium soluble powder.
520.45 Albendazole oral dosage forms.
520.45a Albendazole suspension.
520.45b Albendazole paste.
520.48 Altrenogest solution.
520.62 Aminopentamide hydrogen sulphate tablets.
520.82 Aminopropazine fumarate oral dosage forms.
520.82a Aminopropazine fumarate tablets.
520.82b Aminopropazine fumarate, neomycin sulfate tablets.
520.88 Amoxicillin oral dosage forms.
520.88a Amoxicillin trihydrate film-coated tablets.
520.88b Amoxicillin trihydrate for oral suspension.
520.88c Amoxicillin trihydrate oral suspension.
520.88d Amoxicillin trihydrate soluble powder.
520.88e Amoxicillin trihydrate boluses.
520.88f Amoxicillin trihydrate tablets.
520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.
520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.
520.90 Ampicillin oral dosage forms.
520.90a Ampicillin capsules.
520.90b Ampicillin trihydrate tablets.
520.90c Ampicillin trihydrate capsules.
520.90d Ampicillin trihydrate for oral suspension.
520.90e Ampicillin trihydrate soluble powder.
520.90f Ampicillin trihydrate boluses.
520.100 Amprolium oral dosage forms.
520.100a Amprolium drinking water.
520.100b Amprolium drench.
520.100c Amprolium crumbles.
520.110 Apramycin sulfate soluble powder.
520.154 Bacitracin oral dosage forms.
520.154a Soluble bacitracin methylene disalicylate.
520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.
520.154c Bacitracin zinc soluble powder.
520.182 Bicyclohexylammonium fumagillin.
520.222 Bunamidine hydrochloride.
520.246 Butorphanol tartrate tablets.
520.260 *n*-Butyl chloride capsules.
520.300 Cambendazole oral dosage forms.
520.300a Cambendazole suspension.
520.300b Cambendazole pellets.
520.300c Cambendazole paste.
520.309 Carprofen.
520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.
520.312 Carnidazole tablets.
520.314 Cefadroxil tablets.
520.315 Cefadroxil powder for oral suspension.
520.390 Chloramphenicol oral dosage forms.
520.390a Chloramphenicol tablets.
520.390b Chloramphenicol capsules.
520.390c Chloramphenicol palmitate oral suspension.
520.420 Chlorothiazide tablets and boluses.
520.434 Chlorphenesin carbamate tablets.
520.445 Chlortetracycline oral dosage forms.
520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.
520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).
520.445c Chlortetracycline tablets and boluses.
520.446 Clindamycin hydrochloride capsules.
520.447 Clindamycin hydrochloride liquid.
520.452 Clenbuterol syrup.
520.455 Clomipramine hydrochloride tablets.
520.462 Clorsulon drench.
520.530 Cythioate oral liquid.
520.531 Cythioate tablets.
520.534 Decoquinate.
520.540 Dexamethasone oral dosage forms.
520.540a Dexamethasone powder.
520.540b Dexamethasone tablets and boluses.
520.540c Dexamethasone chewable tablets.
520.550 Dextrose/glycine/electrolyte.
520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.
520.580 Dichlorophene and toluene capsules.
520.581 Dichlorophene tablets.
520.600 Dichlorvos.
520.608 Dicloxacillin sodium monohydrate capsules.
520.620 Diethylcarbamazine oral dosage forms.

520.622 Diethylcarbamazine citrate oral dosage forms.
520.622a Diethylcarbamazine citrate tablets.
520.622b Diethylcarbamazine citrate syrup.
520.622c Diethylcarbamazine citrate chewable tablets.
520.622d Diethylcarbamazine citrate capsules.
520.623 Diethylcarbamazine citrate, oxibendazole chewable tablets.
520.645 Difloxacin.
520.763 Dithiazanine iodide oral dosage forms.
520.763a Dithiazanine iodide tablets.
520.763b Dithiazanine iodide powder.
520.763c Dithiazanine iodide and piperazine citrate suspension.
520.784 Doxylamine succinate tablets.
520.804 Enalapril tablets.
520.812 Enrofloxacin tablets.
520.813 Enrofloxacin oral solution.
520.816 Epsiprantel tablets.
520.823 Erythromycin phosphate.
520.863 Ethylisobutrazine hydrochloride tablets.
520.870 Etodolac.
520.903 Febantel oral dosage forms.
520.903a Febantel paste.
520.903b Febantel suspension.
520.903c [Reserved]
520.903d Febantel-praziquantel paste.
520.903e Febantel tablets.
520.905 Fenbendazole oral dosage forms.
520.905a Fenbendazole suspension.
520.905b Fenbendazole granules.
520.905c Fenbendazole paste.
520.905d Fenbendazole powder.
520.905e Fenbendazole blocks.
520.960 Flumethasone tablets.
520.970 Flunixin oral dosage forms.
520.970a Flunixin meglumine granules.
520.970b Flunixin meglumine paste.
520.1010 Furosemide oral dosage forms.
520.1010a Furosemide tablets or boluses.
520.1010b Furosemide powder.
520.1010c Furosemide syrup.
520.1044 Gentamicin sulfate oral dosage forms.
520.1044a Gentamicin sulfate oral solution.
520.1044b Gentamicin sulfate pig pump oral solution.
520.1044c Gentamicin sulfate soluble powder.
520.1100 Griseofulvin.
520.1120 Haloxon oral dosage forms.
520.1120a Haloxon drench.
520.1120b Haloxon boluses.
520.1130 Hetacillin oral dosage forms.
520.1130a Hetacillin potassium capsules.
520.1130b Hetacillin potassium oral suspension.
520.1130c Hetacillin potassium tablets.
520.1157 Iodinated casein tablets.
520.1158 Iodochlorhydroxyquin boluses.
520.1182 Iron dextran oral suspension.
520.1192 Ivermectin paste.
520.1193 Ivermectin tablets and chewables.
520.1194 Ivermectin drench.
520.1195 Ivermectin liquid.
520.1196 Ivermectin and pyrantel pamoate chewable tablet.
520.1197 Ivermectin sustained-release bolus.
520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.
520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgite tablets.
520.1242 Levamisole hydrochloride oral dosage forms.
520.1242a Levamisole hydrochloride drench and drinking water.
520.1242b Levamisole hydrochloride tablet or oblet (bolus).
520.1242c Levamisole hydrochloride and piperazine dihydrochloride.
520.1242d Levamisole resinate.
520.1242e Levamisole hydrochloride effervescent tablets.
520.1242f Levamisole hydrochloride gel.
520.1242g Levamisole resinate and famphur paste.
520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.
520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.
520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.
520.1263c Lincomycin hydrochloride soluble powder.
520.1284 Sodium liothyronine tablets.
520.1288 Lufenuron tablets.
520.1289 Lufenuron suspension.
520.1310 Marbofloxacin tablets.
520.1320 Mebendazole oral.
520.1326 Mebendazole and trichlorfon oral dosage forms.
520.1326a Mebendazole and trichlorfon powder.
520.1326b Mebendazole and trichlorfon paste.
520.1330 Meclofenamic acid granules.
520.1331 Meclofenamic acid tablets.
520.1341 Megestrol acetate tablets.
520.1380 Methocarbamol tablets.
520.1390 (S)-methoprene.
520.1408 Methylprednisolone tablets.
520.1409 Methylprednisolone, aspirin tablets.
520.1422 Metoserpate hydrochloride.
520.1430 Mibolerone.
520.1445 Milbemycin oxime tablets.
520.1446 Milbemcyin oxime/lufenuron tablets.
520.1448 Monensin oral dosage forms.
520.1448a Monensin blocks.
520.1450 Morantel tartrate oral dosage forms.
520.1450a Morantel tartrate bolus.
520.1450b Morantel tartrate cartridge.
520.1450c Morantel tartrate sustained-release trilaminate cylinder/sheet.
520.1451 Moxidectin.

520.1452 Moxidectin gel.
520.1468 Naproxen granules.
520.1484 Neomycin sulfate soluble powder.
520.1485 Neomycin sulfate oral solution.
520.1510 Nitenpyram.
520.1615 Omeprazole.
520.1616 Orbifloxacin tablets.
520.1628 Oxfendazole powder and pellets.
520.1629 Oxfendazole paste.
520.1630 Oxfendazole suspension.
520.1631 Oxfendazole and trichlorfon paste.
520.1638 Oxibendazole paste.
520.1640 Oxibendazole suspension.
520.1660 Oxytetracycline.
520.1660a Oxytetracycline and carbomycin in combination.
520.1660b Oxytetracycline hydrochloride capsules.
520.1660c Oxytetracycline hydrochloride tablets/boluses.
520.1660d Oxytetracycline hydrochloride soluble powder.
520.1696 Penicillin oral dosage forms.
520.1696a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.
520.1696b Penicillin G potassium in drinking water.
520.1696c Penicillin V potassium for oral solution.
520.1696d Penicillin V potassium tablets.
520.1720 Phenylbutazone oral dosage forms.
520.1720a Phenylbutazone tablets and boluses.
520.1720b Phenylbutazone granules.
520.1720c Phenylbutazone paste.
520.1720d Phenylbutazone gel.
520.1802 Piperazine-carbon disulfide complex oral dosage forms.
520.1802a Piperazine-carbon disulfide complex suspension.
520.1802b Piperazine-carbon disulfide complex boluses.
520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.
520.1803 Piperazine citrate capsules.
520.1804 Piperazine phosphate capsules.
520.1805 Piperazine phosphate with thenium closylate tablets.
520.1806 Piperazine monohydrochloride liquid.
520.1807 Piperazine.
520.1840 Poloxalene.
520.1846 Polyoxyethylene (23) lauryl ether blocks.
520.1870 Praziquantel tablets.
520.1871 Praziquantel/pyrantel pamoate tablets.
520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.
520.1880 Prednisolone tablets.
520.1900 Primidone tablets.
520.1920 Prochlorperazine, isopropamide sustained release capsules.
520.1921 Prochlorperazine, isopropamide, with neomycin sustained-release capsules.
520.1962 Promazine hydrochloride.
520.2002 Propiopromazine hydrochloride.
520.2041 Pyrantel pamoate chewable tablets.
520.2042 Pyrantel pamoate tablets.
520.2043 Pyrantel pamoate suspension.
520.2044 Pyrantel pamoate paste.
520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.
520.2087 Roxarsone soluble powder.
520.2088 Roxarsone tablets.
520.2089 Roxarsone liquid.
520.2095 Sarafloxacin soluble powder.
520.2098 Selegiline hydrochloride tablets.
520.2100 Selenium, vitamin E capsules.
520.2122 Spectinomycin dihydrochloride oral solution.
520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.
520.2123a Spectinomycin dihydrochloride pentahydrate tablets.
520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.
520.2150 Stanozolol oral dosage forms.
520.2150a Stanozolol tablets.
520.2150b Stanozolol chewable tablets.
520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.
520.2158a Streptomycin sulfate oral solution.
520.2158b Dihydrostreptomycin tablets.
520.2158c Dihydrostreptomycin oral suspension.
520.2160 Styrylpyridinium, diethylcarbamazine oral dosage forms.
520.2170 Sulfabromomethazine sodium boluses.
520.2184 Sodium sulfachloropyrazine monohydrate.
520.2200 Sulfachlorpyridazine oral dosage forms.
520.2200a Sulfachlorpyridazine bolus.
520.2200b Sulfachlorpyridazine medicated milk and drinking water.
520.2200c Sulfachlorpyridazine tablets.
520.2220 Sulfadimethoxine oral dosage forms.
520.2220a Sulfadimethoxine oral solution and soluble powder.
520.2220b Sulfadimethoxine tablets and boluses.
520.2220c Sulfadimethoxine oral suspension.
520.2220d Sulfadimethoxine-ormetoprim tablets.
520.2240 Sulfaethoxypyridazine.
520.2240a Sulfaethoxypyridazine drinking water.
520.2240b Sulfaethoxypyridazine tablets.
520.2260 Sulfamethazine oral dosage forms.
520.2260a Sulfamethazine oblet, tablet, and bolus.
520.2260b Sulfamethazine sustained-release boluses.
520.2260c Sulfamethazine sustained-release tablets.
520.2261 Sulfamethazine sodium oral dosage forms.

520.2261a Sulfamethazine sodium drinking water solution.
520.2261b Sulfamethazine sodium soluble powder.
520.2280 Sulfamethizole and methenamine mandelate tablets.
520.2320 Sulfanitran and aklomide in combination.
520.2325 Sulfaquinoxaline oral dosage forms.
520.2325a Sulfaquinoxaline drinking water.
520.2325b Sulfaquinoxaline drench.
520.2330 Sulfisoxazole tablets.
520.2345 Tetracycline oral dosage forms.
520.2345a Tetracycline hydrochloride capsules.
520.2345b Tetracycline tablets.
520.2345c Tetracycline boluses.
520.2345d Tetracycline hydrochloride soluble powder.
520.2345e Tetracycline oral liquid.
520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.
520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.
520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.
520.2362 Thenium closylate tablets.
520.2380 Thiabendazole oral dosage forms.
520.2380a Thiabendazole top dressing and mineral protein feed block.
520.2380b Thiabendazole drench or oral paste.
520.2380c Thiabendazole bolus.
520.2380d Thiabendazole, piperazine citrate suspension.
520.2380e Thiabendazole with trichlorfon.
520.2380f Thiabendazole, piperazine phosphate powder.
520.2455 Tiamulin soluble powder.
520.2456 Tiamulin liquid concentrate.
520.2460 Ticarbodine oral dosage forms.
520.2460a Ticarbodine tablets.
520.2460b Ticarbodine capsules.
520.2473 Tioxidazole oral dosage forms.
520.2473a Tioxidazole granules.
520.2473b Tioxidazole paste.
520.2481 Triamcinolone acetonide tablets.
520.2482 Triamcinolone acetonide oral powder.
520.2520 Trichlorfon oral dosage forms.
520.2520a Trichlorfon oral.
520.2520b Trichlorfon and atropine.
520.2520e Trichlorofon boluses.
520.2520f Trichlorofon granules.
520.2520g Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.
520.2582 Triflupromazine hydrochloride tablets.
520.2604 Trimeprazine tartrate and prednisolone tablets.
520.2605 Trimeprazine tartrate and prednisolone capsules.
520.2610 Trimethoprim and sulfadiazine tablets.
520.2611 Trimethoprim and sulfadiazine oral paste.
520.2612 Trimethoprim and sulfadiazine oral suspension.
520.2613 Trimethoprim and sulfadiazine powder.
520.2640 Tylosin.

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

SOURCE: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine maleate tablets.

(a) *Sponsors*. See drug labeler codes in § 510.600(c) of this chapter for identification of sponsors as follows:

(1) For No. 000856, use of 5-, 10-, or 25-milligram tablets as in paragraph (b) of this section.

(2) For No. 000010, use of 10- or 25-milligram tablets as in paragraph (c) of this section.

(b) *Conditions of use*. It is used in dogs and cats as follows:

(1) *Indications for use*. It is used in dogs and cats as a tranquilizer.

(2) *Amount*. Dogs: 0.25 to 1.0 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight.

(3) *Limitations*. The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Conditions of use*. It is used in dogs as follows:

(1) *Indications for use*. It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount*. Dogs: 0.25 to 1.0 milligram per pound of body weight.

(3) *Limitations*. The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 44443, Sept. 4, 1981, as amended at 49 FR 49091, Dec. 18, 1984; 52 FR 666, Jan. 8, 1987; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35075, June 30, 1997]

§ 520.44 Acetazolamide sodium soluble powder.

(a) *Specifications*. The drug is in a powder form containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in dogs as an aid in the treatment of mild

congestive heart failure and for rapid reduction of intraocular pressure.[1]

(2) It is administered orally at a dosage level of 5 to 15 milligrams per pound of body weight daily.[1]

(3) For use only by or on the order of a licensed veterinarian.[1]

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a)(1) *Specifications*. The product contains 11.36 percent albendazole.

(2) *Sponsor*. See No. 000069 in § 510.600 of this chapter.

(3) *Related tolerances*. See § 556.34 of this chapter.

(4) *Conditions of use in cattle*—(i) *Amount*. 4.54 milligrams per pound of body weight (10 milligrams per kilogram).

(ii) *Indications for use*. For removal and control of the following internal parasites of cattle: Adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus*, *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations*. Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications*. The product contains 4.55 or 11.36 percent albendazole.

(2) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.34 of this chapter.

(4) *Conditions of use in sheep*—(i) *Amount*. 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).

(ii) *Indications for use*. For removal and control of the following internal parasites of sheep: Adult liver flukes (*Fasciola hepatica*, *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcinta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations*. Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 25115, June 13, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 65711, Dec. 21, 1994; 60 FR 55658, Nov. 2, 1995; 61 FR 4875, Feb. 9, 1996; 64 FR 1504, Jan. 11, 1999]

§ 520.45b Albendazole paste.

(a) *Specifications*. The product contains 30 percent albendazole.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*)); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotmum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest solution.

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

(b) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally at the rate of 1 milliliter per 110 pounds body weight (0.044 milligram per kilogram body weight). Give one dose daily for 15 consecutive days.

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

(3) *Limitations.* For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. The drug is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or smoldering uterine inflammation into a fulminating uterine infection in some instances. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 40887, Sept. 12, 1983, as amended at 55 FR 26431, June 28, 1990; 64 FR 42597, Aug. 5, 1999]

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* Each tablet contains 0.2 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

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.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) *Specifications.* The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

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

(c) *Conditions of use*. (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.[1]

(2) It is administered at a dosage level of 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.[1]

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) *Specifications*. The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.

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

(c) *Conditions of use*. (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.[1]

(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.[1]

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

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

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight, twice a day.

(ii) *Indications for use*. Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(ii) *Indications for use*. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract due to *E. coli;* and skin and soft tissue (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount*. 5 milligrams per pound of body weight twice daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis;* genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis;* and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Cats*—(A) *Amount*. 50 milligrams (5 to 10 milligrams per pound) once daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) *Sponsor*. See Nos. 000031 and 000093 in § 510.600(c) of this chapter.

(1) *Conditions of use*. *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

(iii) *Limitations*. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997]

§ 520.88c Amoxicillin trihydrate oral suspension.

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

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*. *Swine*—(1) *Amount*. 40 milligrams orally, twice a day using a dosing pump.

(2) *Indications for use*. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations*. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. 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.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88d Amoxicillin trihydrate soluble powder.

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

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use*. *Preruminating calves including veal calves*—(1) *Amount*. 400 milligrams per 100 pounds of body weight twice daily.

(2) *Indications for use*. Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations*. Administer by drench or by mixing in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. For use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. 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.

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 5525, Feb. 6, 1997]

§ 520.88e Amoxicillin trihydrate boluses.

(a) *Specifications*. Each bolus contains the equivalent of 400 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use*. *Preruminating calves including veal calves*—(1) *Amount*. 400 milligrams per 100 pounds of body weight twice daily.

(2) *Indications for use*. Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations*. For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. 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.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 62 FR 5526, Feb. 6, 1997]

§ 520.88f Amoxicillin trihydrate tablets.

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

(b) *Sponsor*. See Nos. 000031 or 000093 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight twice a day.

(ii) *Indications for use*. 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.

(iii) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37320, Aug. 18, 1992, as amended at 62 FR 13302, Mar. 20, 1997]

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

(a) *Specifications*. Each tablet contains amoxicillin trihydrate and clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) *Staphylococcus aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Wounds, abscesses, cellulitis, and superficial/juvenile pyoderma: Treat for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen after 5 days of treatment, discontinue therapy and reevaluate diagnosis. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus,* nonbeta-lactamase producing *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella* spp. Also, treatment of urinary tract infections (cystitis) due to susceptible strains of *E. coli.*

(iii) *Limitations.* Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

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

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus,* nonbeta-lactamase *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli.* Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus,* nonbeta-lactamase *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli, Pasteurella multocida,* and *Pasteurella* spp.

(iii) *Limitations.* Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and reevaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

§ 520.90 Ampicillin oral dosage forms.

§ 520.90a Ampicillin capsules.

(a) *Specifications*. Each capsule contains 125 milligrams or 250 milligrams of ampicillin.

(b) *Sponsor*. See No. 000008 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times daily; for animals weighing 6 to 14 pounds, one capsule twice daily.

(ii) *Indications for use*. Treatment of urinary tract infections (cystitis) due to *Proteus* spp., hemolytic and nonhemolytic streptococci, beta hemolytic streptococci, and *Escherichia coli*. In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations*. Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 125 milligrams twice daily; in more acute conditions three times daily.

(ii) *Indications for use*. Treatment of respiratory tract infections (bacterial pneumonia) due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations*. Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992]

§ 520.90b Ampicillin trihydrate tablets.

(a) *Specifications*. Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use*. Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and *Pasteurella* spp., urinary tract infections (cystitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E., coli*, *P. mirabilis*, and *Enterococcus* spp.; gastrointestinal infections due to *Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., and *E. coli*.; infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus* spp., and *Streptococcus* spp.

(3) *Limitations*. Not for use in animals which have shown hypersensitivity to penicillin or for infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 520.90c Ampicillin trihydrate capsules.

(a) *Specifications*. Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight, three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

(iii) *Limitations*. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10 to 30 milligrams per pound of body weight or three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

(iii) *Limitations*. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90d Ampicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted as directed, each milliliter contains ampicillin trihydrate equivalent to 25 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 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.

(ii) *Indications for use*. Treatment of respiratory tract infections (tracheobronchitis and tonsillitis) due to *Escherichia coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., and *Proteus* spp.; bacterial gastroenteritis due to *E. coli*; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp. and *Streptococcus* spp.; bacterial dermatitis due to *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Pseudomonas* spp.

(iii) *Limitations*. 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. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10 to 30 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment of respiratory tract infections (bacterial pneumonia) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Proteus* spp.; urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Corynebacterium* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due

to *Staphylococcus* spp., *Streptococcus* spp., *Bacillus* spp., and *Pasteurella* spp.

(iii) *Limitations*. 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. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90e Ampicillin trihydrate soluble powder.

(a) *Specifications*. Each gram contains ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Swine*—(1) *Amount*. 5 milligrams of ampicillin per pound of body weight twice daily, orally by gavage or in drinking water for up to 5 days.

(2) *Indications for use*. Oral treatment of porcine colibacillosis (*Escherichia coli*) and salmonellosis (*Salmonella* spp.) infections in swine up to 75 pounds of body weight, and bacterial pneumonia caused by *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

(3) *Limitations*. For use in swine only. Not for use in other animals which are raised for food production. 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.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90f Ampicillin trihydrate boluses.

(a) *Specifications*. Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter for use as in paragraph (d)(1), 000069 for use as in paragraph (d)(2).

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Nonruminating calves*—(1) *Amount*. 5 milligrams per pound of body weight twice daily for up to 5 days.

(i) *Indications for use*. Oral treatment of colibacillosis caused by *Escherichia coli*, bacterial enteritis caused by *Salmonella* spp., and bacterial pneumonia caused by *Pasteurella* spp.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount*. 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(i) *Indications for use*. Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli*.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995]

§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) *Chemical name*. 1-(4-Amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

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

(c) *Related tolerances*. See § 556.50 of this chapter.

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

(1) *Chickens and turkeys*—(i) *Amount*. 20 percent soluble powder.

(ii) *Indications for use*. Treatment of coccidiosis.

(iii) *Limitations*. Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024

percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves*—(i) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(*a*) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(*b*) *Limitations*. Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(*b*) *Limitations*. Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.100b Amprolium drench.

(a) *Chemical name*. 1-(4-Amino-2-*n*-propyl - 5 - pyrimidinylmethyl) - 2 - picolinium chloride hydrochloride.

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

(c) *Related tolerances*. See § 556.50 of this chapter.

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

(1) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.100c Amprolium crumbles.

(a) *Specifications*. Amprolium crumbles contain 1.25 percent amprolium.

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

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) *Amount*. 1.6 ounces of crumbles per 250 pounds of body weight per day (5

milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) *Amount.* 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination should be done by a veterinarian or diagnostic laboratory before treatment. When treating outbreaks, the drug should be administered promptly after diagnosis is determined. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

[42 FR 41855, Aug. 19, 1977, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.110 Apramycin sulfate soluble powder.

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use.* (1) In swine for control of porcine colibacillosis (weanling pig scours) caused by strains of *E. coli* sensitive to apramycin.

(2) It is administered for 7 days in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day. Swine will normally consume 1 gallon per day of medicated water containing 375 milligrams of apramycin for each 66 pounds of body weight. Water consumption should be monitored to determine that the required amount of apramycin is being consumed. The drug concentration should be adjusted according to water consumption which varies depending on ambient temperature, humidity, and other factors.

(3) Prepare fresh medicated water daily.

(4) Do not slaughter treated swine for 28 days following treatment

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988]

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Soluble bacitracin methylene disalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Growing turkeys*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler and replacement chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Treponema hyodysenteriae.* Administer

continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations*. Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

(4) *Growing quail*—(i) *Amount*. 400 milligrams per gallon in drinking water.

(ii) *Indications for use*. For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

(iii) *Limitations*. Prepare fresh solution daily. Use as sole source of drinking water.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 63 FR 38474, July 17, 1998; 64 FR 13068, Mar. 17, 1999]

§ 520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.

(a) *Specifications*. Each gram contains 200 units of soluble bacitracin methylene disalicylate, streptomycin sulfate equivalent to 20 milligrams of streptomycin, and 850 milligrams of carob flour.

(b) *Sponsor*. See No. 062925 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use*. Treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

(3) *Limitations*. If no improvement is noted in 2 to 3 days, diagnosis should be reevaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 61 FR 66581, Dec. 18, 1996]

§ 520.154c Bacitracin zinc soluble powder.

(a) *Specifications*. Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.70 of this chapter.

(d) *Conditions of use*. (1) *Broiler chickens*—(i) *Amount*. 100 milligrams per gallon in drinking water.

(A) *Indications for use*. Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(ii) *Amount*. 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use*. Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount*. 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use*. Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

(iii) *Limitations*. Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992]

§ 520.182 Bicyclohexylammonium fumagillin.

(a) *Specifications*. The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) *Sponsor*. See No. 059620 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the prevention of nosema in honey bees.[1]

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar sirup.[1]

(3) Colonies used for package production should be fed medicated sirup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.[1]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(4) The medicated sirup should not be fed immediately before or during the honey flow.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 65151, Dec. 30, 1977; 56 FR 43699, Sept. 4, 1991; 58 FR 5608, Jan. 22, 1993]

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name*. *N,N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications*. The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

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

(d) *Conditions of use*. (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis*.

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 13018, Mar. 8, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.246 Butorphanol tartrate tablets.

(a) *Specifications*. Each tablet contains 1, 5, or 10 milligrams of butorphanol base activity as butorphanol tartrate.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. The drug is used for the treatment of dogs as follows:

(1) *Amount*. 0.25 milligram of butorphanol base activity per pound of body weight.

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

(3) *Limitations*. For oral use in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to a maximum of 0.5 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 14702, Apr. 6, 1982, as amended at 53 FR 27851, July 25, 1988]

§ 520.260 *n*-Butyl chloride capsules.

(a)(1) *Specifications*. *n*-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of *n*-butyl chloride in each capsule.

(2) *Sponsor*. See No. 021091 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs and of the ascarid (*Toxocara cati*) and hookworm (*Ancylostoma tubaeforme*) from cats.

(ii)(*a*) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should be given a repeat treatment in a week or 10 days. After that they should be treated every 2 months (or as symptoms reappear) until a year old. When the puppy or kitten is a year old, one treatment every 3 to 6 months is sufficient.

(*b*) For dogs or cats that have been wormed regularly, treatment every 3 to 6 months will be sufficient. If a dog or cat has not been wormed previously and has the symptoms of large roundworms a dose should be given and repeated in 10 days. Removal of

hookworms may require 3 or 4 doses at 10-day intervals.

(*c*) Puppies, dogs, cats, or kittens weighing 1 to 3 pounds should be given 2 capsules per dose which contain 272 milligrams of *n*-butyl chloride each. Such animals weighing 4 to 5 pounds should be given 3 such capsules. Animals weighing 6 to 7 pounds should be given 4 such capsules and animals weighing 8 to 9 pounds should be given 5 such capsules. Animals weighing 10 to 20 pounds should be given 3 capsules which contain 816 milligrams of *n*-butyl chloride each, animals weighing 20 to 40 pounds should be given 4 such capsules and animals weighing over 40 pounds should be given 5 such capsules with the maximum dosage being 5 capsules, each of which contains 816 milligrams of *n*-butyl chloride.

(iii) A veterinarian should be consulted before using in severely debilitated dogs or cats and also prior to repeated use in cases which present signs of persistent parasitism.

(b)(1) *Specifications*. *n*-Butyl chloride capsules contain 221, 442, 884, or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.[1]

(2) *Sponsors*. See No. 023851 in § 510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 000115 or 038782 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 for 221 milligram capsules.

(3) *Conditions of use*. (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs.[1]

(ii)(*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks.[1]

(*b*) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 1¼ pound of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.[1]

(iii) A veterinarian should be consulted before using in severely debilitated dogs.[1]

(c)(1) *Specifications*. *n*-Butyl chloride capsules, veterinary contain 884 or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.

(2) *Sponsor*. See No. 000115 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancyclostoma caninum*, *Ancyclostoma braziliense*, and *Uncinaria stenocephala*) from dogs.

(ii)(*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal rations may be resumed 4 to 8 hours after treatment.

(*b*) The drug is administered orally to dogs. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: weighing under 5 pounds, 1 capsule; weighing 5–10 pounds, 2 capsules; weighing 10–20 pounds, 3 capsules; weighing 20–40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dogs to dogs weighing 5–10 pounds and 2 capsules per dog to dogs weighing 20–40 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at dosage level of 1 capsule per dog to dogs weighing 40 pounds or over.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999]

§ 520.300 Cambendazole oral dosage forms.

§ 520.300a Cambendazole suspension.

(a) *Specifications*. Each fluid ounce contains 0.9 gram of cambendazole.

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

(c) *Conditions of use*. (1) It is used in horses 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*).

(2) It is administered 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).

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

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

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.300b Cambendazole pellets.

(a) *Specifications*. The drug is in feed pellets containing 5.3 percent cambendazole.

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

(c) *Conditions of use*. (1) It is used in horses 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*).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.300c Cambendazole paste.

(a) *Specifications*. The drug is a paste containing 45 percent cambendazole.

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

(c) *Conditions of use*. (1) It is used in horses 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*).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.309 Carprofen.

(a) *Specifications*. Each caplet or chewable tablet contains 25, 75, or 100 milligrams of carprofen.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount*. 1 milligram per pound of body weight twice daily. Caplets and chewable tablets are scored and dosage should be calculated and given in half-caplet or half-chewable tablet increments.

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

(3) *Limitations*. The safe use of carprofen in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. As a class, cyclo-oxygenase inhibitory nonsteroidal anti-inflammatory drugs (NSAID's) may be associated with gastrointestinal and renal toxicity. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Because many NSAID's possess the potential to induce gastrointestinal ulceration, avoid or closely monitor concomitant use of carprofen with other anti-inflammatory drugs, such as corticosteroids and NSAID's. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in safety studies of up to 10 times the dose in dogs. Do not use in dogs with bleeding disorders (e.g., Von Willebrand's disease). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999]

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of 5stcaramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.[1]

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.[1]

(2) *Indications for use*. For relief of cough.[1]

[43 FR 55385, Nov. 28, 1978]

§ 520.312 Carnidazole tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor*. See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use*. For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations*. Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989]

§ 520.314 Cefadroxil tablets.

(a) *Specifications*. 50-, 100-, and 200-milligram tablets for dogs and cats; 1 gram tablet for dogs.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) For use in dogs as follows:

(i) *Indications for use*. For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*.

(ii) *Amount*. Ten milligrams per pound of body weight twice daily.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(iii) *Limitations*. The drug is administered orally. For skin and soft tissue infections, treatment should be continued for a minimum of 3 days. For genitourinary tract infections, treatment should be continued for a minimum of 7 days. Continue treatment at least 48 hours after the dog has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 30 days. Safety for use in pregnant bitches and stud dogs has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) For use in cats as follows:

(i) *Indications for use*. For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(ii) *Amount*. Ten milligrams per pound of body weight once daily.

(iii) *Limitations*. The drug is administered orally. Continue treatment at least 48 hours after the cat has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 21 days. Safety for use in pregnant cats and breeding male cats has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 41105, Sept. 17, 1982, as amended at 49 FR 43052, Oct. 26, 1984; 51 FR 4165, Feb. 3, 1986; 52 FR 11989, Apr. 14, 1987; 53 FR 27851, July 25, 1988]

§ 520.315 Cefadroxil powder for oral suspension.

(a) *Specifications*. Cefadroxil powder is reconstituted to form a 50 milligram-per-milliliter aqueous suspension.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) For use in dogs as follows:

(i) *Indications for use*. For treating genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus;* and skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses caused by susceptible strains of *Staphylococcus aureus*.

(ii) *Amount*. 10 milligrams per pound of body weight, twice daily.

(2) For use in cats as follows:

(i) *Indications for use*. For treating skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(ii) *Amount*. 10 milligrams per pound of body weight, once daily.

(3) *Limitations*. Discard unused portion of reconstituted product after 14 days. Treatment should continue for 48 hours after animal is afebrile or asymptomatic. If no response after 3 days, discontinue treatment and reevaluate therapy. Not for use in animals raised for food production. Safe use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 FR 27344, July 20, 1988]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) *Specifications*. Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) *Sponsor*. In § 510.600(c) of this chapter: No. 000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-. and 500-milligram tablets; No. 017030 for 100-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) *Conditions of use*. *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use*. Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(iii) *Limitations*. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on

samples collected prior to treatment. If no response to chloramphenicol therapy is obtained in 3 to 5 days, discontinue its use and review diagnosis. Not for animals which are raised for food production. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each tablet contains 50, 100, 250, or 500 milligrams, or 1 gram of chloramphenicol.

(2) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(3) *Conditions of use. Dogs*—(i) *Amount.* 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use.* Oral treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(iii) *Limitations.* Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis. Not for animals that are raised for food production. Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery. Chloramphenicol should not be administered to dogs maintained for breeding purposes. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992, as amended at 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001]

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams of chloramphenicol.

(b) *Sponsor.* (1) For chloramphenicol capsules containing 50, 100, 250, or 500 milligrams of chloramphenicol see Nos. 000069, 000185, and 027454 in § 510.600(c) of this chapter.

(2) For chloramphenicol capsules containing 100 or 250 milligrams of chloramphenicol see No. 058034 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight every 6 hours.

(2) *Indications for use.* Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(3) *Limitations.* Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. This product must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992, as amended at 63 FR 5255, Feb. 2, 1998]

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) *Specifications.* Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight every 6 hours. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals that are raised for food production. Must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or

tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.420 Chlorothiazide tablets and boluses.

(a)(1) *Specifications*. Each tablet contains 0.25 gram of chlorothiazide.

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

(3) *Conditions of use*—(i) *Amount*. Usual dosage is 5 to 10 milligrams per pound of body weight two or three times daily.[1]

(ii) *Indications for use*. For use in dogs for treatment of congestive heart failure and renal edema.[1]

(iii) *Limitations*. *(a)* Dosage must be adjusted to meet the changing needs of the individual animal. In mild and responsive cases, it is suggested that a dose of 5 milligrams per pound of body weight be administered two or three times daily. In moderately edematous and moderately responsive animals, a dose of 7.5 to 10 milligrams per pound of body weight may be administered three times daily. Severe conditions may require higher doses. Certain animals may respond adequately to intermittent therapy; in these cases, the drug may be administered either every other day or for 3 to 5 days each week.

(*b*) Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. In some dogs, hypochloremic alkalosis may occur (that is, excretion of chloride in relation to sodium is excessive; the plasma bicarbonate level increases and alkalosis results). Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

(b)(1) *Specifications*. Each bolus contains 2 grams of chlorothiazide.

(2) *Sponsor*. See No. 000006 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 2 grams once or twice daily for 3 or 4 days.[1]

(ii) *Indications for use*. For use in cattle as an aid in reduction of postparturient udder edema.[1]

(iii) *Limitations*. Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. Milk taken from dairy animals during treatment and for 72 hours (six 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.[1]

[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.434 Chlorphenesin carbamate tablets.

(a) *Specifications*. Each tablet contains 400 milligrams of chlorphenesin carbamate.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 50 milligrams per pound of body weight on first day; 25 milligrams per pound of body weight each following day. Divide total daily dose into 2 or 3 equal doses—administer at 12- or 8-hour intervals.

(2) *Indications for use*. For use as an adjunct to therapy of acute inflammatory and traumatic conditions of skeletal muscles. The drug provides relief of the signs of discomfort associated with myositis, muscle sprains, traumatic injuries, stifle injuries—especially when administered before or after surgery—and invertebral disc syndrome (can be used concurrently with adrenal corticosteroids).

(3) *Limitations*. Not recommended for pregnant animals or those with a known hepatic dysfunction. Periodic liver function studies are recommended for animals on prolonged treatment. If no response is evident within 5 days of the beginning of treatment, the diagnosis should be redetermined and appropriate therapy instituted. Not recommended for use with general anesthetics other than the barbiturates. Federal law restricts this drug to use

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

by or on the order of a licensed veterinarian.

[44 FR 16009, Mar. 16, 1979]

§ 520.445 Chlortetracycline oral dosage forms.

§ 520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.

(a) *Specifications*. Each pound contains chlortetracycline bisulfate equivalent to 102.4 grams of chlortetracycline hydrochloride with sulfamethazine bisulfate equivalent to 102.4 grams of sulfamethazine.

(b) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use*. *Swine*—Used in drinking water as follows:

(1) *Amount*. 250 milligrams of chlortetracycline with 250 milligrams of sulfamethazine per gallon.

(2) *Indications for use*. Prevention and treatment of bacterial enteritis; aid in the reduction of the incidence of cervical abscesses; aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations*. Not to be used for more than 28 consecutive days; withdraw 15 days before slaughter; as sole source of chlortetracycline and sulfonamide.

[57 FR 37323, Aug. 18, 1992]

§ 520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).

(a) *Specifications*. Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

(b) *Sponsors*. See No. 053389 in § 510.600(c) of this chapter for conditions of use as in paragraphs (d)(1)(i)(A) and (d)(2)(i)(A) of this section; No. 010042 for conditions of use as in paragraph (d)(4) of this section; No. 000010 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) through (iv) of this section; Nos. 017519 and 059130 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) and (iii) of this section.

(c) *Related tolerances*. See § 556.150 of this chapter.

(d) *Conditions of use*. (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount*. Ten milligrams per pound of body weight daily in divided doses.

(1) Indications for use. Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) Limitations. Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount*. Ten milligrams per pound of body weight daily in divided doses.

(1) Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) Limitations. Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount*. 200 to 400 milligrams per gallon.

(*1*) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae*.

(*2*) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(B) *Amount*. 400 to 800 milligrams per gallon.

(*1*) *Indications for use*. Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli*.

(*2*) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(C) *Amount*. One thousand milligrams per gallon.

(1) Indications for use. Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(2) Limitations. See paragraph (d)(4)(i)(A)(*2*) of this section.

(ii) *Growing turkeys*—(A) *Amount*. 400 milligrams per gallon.

(*1*) *Indications for use*. Control of infectious synovitis caused by *M. synoviae*.

(*2*) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(B) *Amount*. 25 milligrams per pound of body weight daily.

(*1*) *Indications for use*. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(*2*) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(iii) *Swine*—(A) *Amount*. 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days; for 000010, 012286, and 053389 do not slaughter animals for food within 5 days of treatment; for 010042 do not slaughter animals for food within 24 hours of treatment.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 milligrams per pound daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 61015, Nov. 19, 1993; 59 FR 39439, Aug. 3, 1994; 60 FR 26827, May 19, 1995; 60 FR 47052, Sept. 11, 1995; 62 FR 27691, May 21, 1997; 62 FR 35076, June 30, 1997; 62 FR 60656, Nov. 12, 1997; 64 FR 37673, July 13, 1999; 65 FR 10706, Feb. 29, 2000]

§ 520.445c Chlortetracycline tablets and boluses.

(a) *Specifications*. Each tablet/bolus contains 25, 250, or 500 milligrams of chlortetracycline hydrochloride.

(b) *Sponsors*. See No. 000010 in § 510.600(c) of this chapter for the 250-milligram chlortetracycline hydrochloride bolus; see No. 010042 for the 25-milligram tablet and the 500 milligram bolus.

(c) *Related tolerances*. See § 556.150 of this chapter.

(d) *National Academy of Sciences/National Research Council NAS/NRC) status*. The conditions of use specified in this section were NAS/NRC reviewed and

found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(e) *Conditions of use. Calves*—(1) *Amount*. One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klesbsiella* spp., and *Hemophilus* spp.

(ii) *Limitations*. Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount*. One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount*. One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992]

§ 520.446 Clindamycin hydrochloride capsules.

(a) *Specifications*. Each capsule contains the equivalent of 25, 75, or 150 milligrams of clindamycin as the hydrated hydrochloride salt.

(b) *Sponsor*. No 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use*. For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*.

(3) *Limitations*. Wound infections, abscesses, and dental infections: Do not use more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, and horses. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 23341, June 6, 1984, as amended at 51 FR 34960, Oct. 1, 1986; 54 FR 47767, Nov. 17, 1989]

§ 520.447 Clindamycin hydrochloride liquid.

(a) *Specifications*. Each milliliter of 8.64 percent alcoholic solution contains the equivalent of 25 milligrams of clindamycin (as the hydrochloride).

(b) *Sponsor*. See Nos. 000009 and 059130 in § 510.600(c) of this chapter for use as in paragraphs (c) and (d) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use*. For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*.

(3) *Limitations*. Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use in cats*—(1) *Amount*. 5.0 to 10.0 milligrams per pound of body weight every 24 hours for a maximum of 14 days (11 to 22 milligrams per kilogram of body weight per day).

(2) *Indications for use*. Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus, S. intermedius, and Streptococcus spp*. Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*.

(3) *Limitations*. Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 21239, May 23, 1985, as amended at 51 FR 34960, Oct. 1, 1986; 54 FR 47766, Nov. 17, 1989; 61 FR 59003, Nov. 20, 1996; 62 FR 46669, Sept. 4, 1997; 66 FR 13848, Mar. 8, 2001]

§ 520.452 Clenbuterol syrup.

(a) *Specifications*. Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use*. Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations*. Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food

animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine hydrochloride tablets.

(a) *Specifications*. Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use*. For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

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

[64 FR 1762, Jan. 12, 1999]

§ 520.462 Clorsulon drench.

(a) *Specifications*. The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

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

(c) *Conditions of use*. *Cattle*—(1) *Amount*. One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use*. For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations*. Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.530 Cythioate oral liquid.

(a) *Specifications*. Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor*. See Nos. 000859 and 010042 in § 510.600 of this chapter.

(c) *Special considerations*. Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount*. 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use*. Dogs, for control of fleas.

(3) *Limitations*. For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984]

§ 520.531 Cythioate tablets.

(a) [Reserved]

(b) *Sponsors*. See No. 000859 in § 510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 010042 in § 510.600(c) of this chapter for use of 30-mg tablet.

(c) *Special considerations*. Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount*. 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use*. Dogs, for control of fleas.

(3) *Limitations*. For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5615, Feb. 14, 1984, as amended at 59 FR 26942, May 25, 1994]

§ 520.534 Decoquinate.

(a) *Specifications*. The drug is a powder containing 0.8 percent decoquinate.

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.170 of this chapter.

(d) *Conditions of use*. *Calves*—(1) *Amount*. Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use*. For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*.

(3) *Limitations*. Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

[64 FR 10103, Mar. 2, 1999, as amended at 64 FR 30386, June 8, 1999]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications*. Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

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

(c) *Conditions of use*. (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy 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.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

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

[40 FR 13838, Mar. 27, 1975; 41 FR 9149, Mar. 3, 1976; 52 FR 7832, Mar. 13, 1987]

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications*. Each bolus is half-scored and contains 10 milligrams of dexamethasone.

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

(3) *Conditions of use*. (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (cushingoid syndrome), except for emergency therapy.

(v) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

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

(b)(1) *Specifications*. Each tablet contains 0.25 milligram of dexamethasone.[1]

(2) *Sponsors*. See Nos. 000061 and 061133 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Dogs: Administer orally at 0.25 to 1.25 milligrams per day for up to 7 days. Cats: 0.125 to 0.5 milligram per day for up to 7 days.[1]

(ii) *Indications for use.* In treatment of dogs and cats as an anti-inflammatory agent.[1]

(iii) *Limitations.* (*a*) Clinical and experimental data have demonstrated that corticosteriods administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy; and they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(*b*) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers, except for emergency therapy.[1]

(*c*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 26273, June 23, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 50 FR 49372, Dec. 2, 1985; 52 FR 7832, Mar. 13, 1987; 55 FR 8461, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001]

§ 520.540c Dexamethasone chewable tablets.

(a) *Specifications.* Each half-scored tablet contains 0.25 milligram of dexamethasone.[1]

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 0.25 to 1.25 milligrams per day.[1]

(2) *Indications for use.* Supportive therapy in nonspecific dermatosis and inflammatory conditions in dogs.[1]

(3) *Limitations.* (i) Administer by free-choice feeding or crumble over food. Administer 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.

(ii) Clinical and experimental data have demonstrated that corticosteriods administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy; and they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iii) Do not use in viral infections. Anti-inflammatory action of corticosteriods may mask signs of infection. Do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers, except for emergency therapy.[1]

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

[44 FR 7130, Feb. 6, 1979, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.550 Dextrose/glycine/electrolyte.

(a) *Specifications.* The product is distributed in packets each of which contains the following ingredients: sodium chloride 8.82 grams, potassium phosphate 4.20 grams, citric acid anhydrous 0.5 gram, potassium citrate 0.12 gram, aminoacetic acid (glycine) 6.36 grams, and dextrose 44.0 grams.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dextrose/glycine/electrolyte is indicated for use in the control of dehydration associated with diarrhea (scours) in calves. It is used as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(2) Dissolve each packet in two 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.

(3) The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. Oral therapy in these cases is

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

too slow. Animals which cannot drink after initial intravenous therapy may need to be dosed with a stomach tube or esophageal tube. Adequate colostrum intake during the first 12 hours is essential for healthy, vigorous calves. Antibacterial therapy is often indicated in bacterial scours due to *E. coli* and/or *Salmonella*. The product does not contain antibacterial agents. A veterinarian should be consulted in severely scouring calves or cases requiring antibacterial therapy. 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.

[48 FR 38606, Aug. 25, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.

(a) *Specifications*. Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats.

(2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

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

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.580 Dichlorophene and toluene capsules.

(a) *Specifications*. Each soft gelatin capsule contains 50 milligrams of dichlorophene and 60 milligrams of toluene or multiples thereof. [1]

(b) *Sponsor*. (1) For single dose only, see 000010, 000061, 000115, 000842, 011615, 017135, 023851, 049968, 050906, and 058670 in § 510.600(c) of this chapter.

(2) For single and multiple dose, see 000010, 000061, and 038782 in § 510.600(c) of this chapter.

(c) *Required statement*. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use*—(1) *Amount*. (i) Single dose of 100 milligrams of dicholorophene and 120 milligrams of toluene per pound of body weight.[1]

(ii) Divided dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per 5 pounds of body weight (20 and 24 milligrams per pound) daily for 6 days.[1]

(2) *Indications for use*. It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) and as an aid in removing tapeworms (*Taenia pisiformis*, *Dipylidium caninum*, and *Echinococcus granulosus*) from dogs and cats.[1]

(3) *Limitations*. Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward. Repeat treatment in 2 to 4 weeks in animals subject to reinfection.[1]

[45 FR 10332, Feb. 15, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.580, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.581 Dichlorophene tablets.

(a) *Specifications*. Each tablet contains 1 gram of dichlorophene.

(b) *Sponsor*. See 023851 in § 510.600(c) of this chapter.

(c) *Required statement*. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use*. *Dogs*—(1) *Amount*. Single dose of 1 tablet (1 gram of dichlorophene) for each 10 pounds of body weight.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Indications for use*. It is used as an aid in the removal of tapeworms (*Taenia pisiformis* and *Dipylidium caninum*).

(3) *Limitations*. Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward.

[45 FR 10333, Feb. 15, 1980]

§ 520.600 Dichlorvos.

(a) *Chemical name*. 2,2-Dichlorvinyl dimethyl phosphate.

(b) [Reserved]

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

(d) *Related tolerances*. See § 556.180 of this chapter.

(e) *Conditions of use in swine*. (1) It is recommended for the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* spp.), large round-worm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(2) The preparation should be added to the indicated amount of feed as set forth in paragraph (e)(2) of this section and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.08 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.08 ounce of dichlorvos
20–30	4	0.33	12
31–40	5	0.56	9
41–60	6	1.00	6
61–80	5	1.00	5
81–100	4	1.00	4
Adult Gilts, Sows, and Boars	16	4.00	4

(3) Do not use this product on animals either simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(f) *Conditions of use in dogs*. (1) For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

(2) The drug is in capsule form for direct administration and in pellet form for administration in about one-third of the regular canned dog food ration or in ground meat. Dogs may be treated with any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 milligrams of the active ingredient per pound of body weight. One-half of the single recommended dosage may be given, and the other half may be administered 8 to 24 hours later. This split dosage schedule should be used in animals which are very old, heavily parasitized, anemic, or otherwise debilitated. The drug should not be used in dogs weighing less than 2 pounds.

(3) In some dogs, efficacy against *Trichurias vulpis* (whipworm) may be erratic. Dogs that do not develop a negative stool for *Trichuris vulpis* ova 10 to 14 days following initial treatment should be re-treated. If a negative stool is not obtained in 10 to 14 days following re-treatment, alternate means of therapy should be considered.

(4) Do not use in dogs infected with *Dirofilaria immitis*.

(5) Do not use with other anthelmintics, taeniacides, antifilarial agents, muscle relaxants, or tranquilizers.

(6) The drug is a cholinesterase inhibitor. Not for use simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

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

(g) *Conditions of use in horses when administered in grain*. (1) It is recommended for the removal and control of bots (*Gastrophilus intestinalis*, *G. nasalis*), large strongyles (*Strongylus*

vulgaris, *S. equinus*, *S. edentatus*), small strongyles (of the genera *Cyathostomum*, *Cylicocercus*, *Cylicocyclus*, *Cylicodontophorus*, *Triodontophorus*, *Poteriostomum*, *Gyalocephalus*), pinworms (*Oxyuris equi*), and large roundworm (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(2) For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or a diagnostic laboratory prior to worming.

(3) It is administered in the grain portion of the ration at a dosage of 14.2 milligrams to 18.5 milligrams per pound of body weight as a single dose. It may be administered at one-half of the single recommended dosage and repeated 8 to 12 hours later in the treatment of very aged, emaciated or debilitated subjects or those reluctant to consume medicated feed. In suspected cases of severe ascarid infection sufficient to cause concern over mechanical blockage of the intestinal tract, the split dosage should be utilized.

(4) Do not use in horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia or colic. Do not administer in conjunction with or within 1 week of administration of muscle relaxant drugs, phenothiazine derived tranquilizers or central nervous system depressant drugs. Horses should not be subjected to insecticide treatment for 5 days prior to or after treating with the drug. Do not administer to horses afflicted with chronic alveolar emphysema (heaves) or related respiratory conditions. The product is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals.

(5) Do not use in animals other than horses, ponies, and mules. Do not use in horses, ponies, and mules intended for food purposes. Do not allow fowl access to feed containing this preparation or to fecal excrement from treated animals.

(h) *Conditions of use in horses when administered orally by syringe.* (1) It is recommended for the removal and control of first, second, and third instar bots (*Gastrophilus intestinalis* and *G. nasalis*), sexually mature and sexually immature (4th stage) ascarids (*Parascaris equorum*) in horses and foals.

(2) The product is in the form of a gel which is administered directly from a syringe onto the horse's tongue. The product is administered at a dosage level of 20 milligrams of dichlorvos per kilogram of body weight for the removal of bots and ascarids. The same dosage level is repeated every 21 to 28 days for the control of bots and ascarids. For the control of bots only, the repeat dosage is 10 milligrams per kilogram of body weight every 21 to 28 days during bot fly season.

(3) Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides or chemicals. Do not administer in conjunction with or within 1 week of administration of muscle-relaxant drugs, phenothiazine derived tranquilizers, or central nervous system depressants.

(4) Do not use in horses which are severly debilitated or suffering from diarrhea or severe constipation, infectious disease, toxemia, or colic. Do not administer to horses affected with chronic alveolar emphysema (heaves) or other respiratory conditions.

(5) Do not use in horses intended for food purposes.

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

(i) *Conditions of use in dogs, cats, puppies, and kittens.* (1) Each tablet contains 2, 5, 10, or 20 milligrams of dichlorvos.

(2) It is administered orally at 5 milligrams of dichlorvos per pound of body weight.

(3) Dogs and puppies: Removal and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(4) Cats and kittens: Removal and control of intestinal roundworms (*Toxocara cati* and *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme* and *Uncinaria stenocephala*).

(5) Dichlorvos is a cholinesterase inhibitor. Do not use simultaneously with or within a few days before or

after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(6) Do not use in animals under 10 days of age or 1 pound of body weight.

(7) Do not administer to animals showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or recently exposed to or showing signs of infectious disease.

(8) Do not use in dogs or puppies infected with *Dirofilaria immitis*.

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

[40 FR 13838, Mar. 27, 1975, as amended at 48 FR 40704, Sept. 9, 1983; 51 FR 28546, Aug. 8, 1986; 62 FR 35076, June 30, 1997; 64 FR 18571, Apr. 15, 1999]

§ 520.608 Dicloxacillin sodium monohydrate capsules.

(a) *Specifications*. Each capsule contains dicloxacillin sodium monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin.

(b) *Sponsor*. See No. 000856 in § 510.600 (c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount*. 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*. Treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to the drug.

(3) *Limitations*. For the treatment of dogs only. Continue treatment for 24 to 48 hours after the animal has become afebrile or asymptomatic, Administer 1 to 2 hours before feeding to ensure maximum absorption. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992]

§ 520.620 Diethylcarbamazine oral dosage forms.

§ 520.622 Diethylcarbamazine citrate oral dosage forms.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) *Sponsors*. (1) See 015579 in § 510.600(c) of this chapter for use of 50, 200, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(2) See 053501 in § 510.600(c) of this chapter for use of 100, 200, and 300 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs.

(3) See 061133 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(4) See 017030 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(5) See 000081 in § 510.600(c) of this chapter for use of 60, 120, or 180 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(6) See No. 000010 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use*—(1) *Dosage/indications for use*. (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

(2) *Limitations*. Administer orally either pulverized and given in feed or water or directly by mouth. For the treatment of ascarid infections, repeat in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions because of pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001]

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications*. Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

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

(b)(1) *Specifications*. Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsors*. (i) See No. 017030 for use as in paragraphs (b)(3)(ii)(*a*) and (b)(3)(ii)(*c*) of this section.

(ii) See No. 017030 for use as in paragraphs (b)(3)(ii) (*a*) and (*c*) of this section.

(3) *Conditions of use*—(i) *Amount*. 3 milligrams per pound of body weight per day for prevention of heartworm disease and as an aid in control of large roundworms; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(ii) *Indications for use*. (*a*) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(*b*) As an aid in control of large roundworms (*T. canis*) in dogs.

(*c*) As an aid in treatment of ascarid infections in dogs (*T. canis*) and cats (*T. canis* and *T. leonina*).

(iii) *Limitations*. The drug may be placed on the daily ration or given directly by mouth. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Older dogs should be proven negative for presence of *Dirofilaria immitis* infections before administering the drug. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs.

Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start 1 month before the mosquito season and be continued daily throughout the mosquito season and for 2 months thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications*. Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

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

(3) *Conditions of use*. (i) The drug is used in dogs between 4 weeks and 8 months of age for the removal of ascarids (*Toxacara canis*) and in animals over 4 weeks of age for the prevention of heartworm disease (*Dirofilaria immitis*).

(ii) The drug is administered (*a*) for removal of ascarids at a dosage of 50 milligrams per pound of body weight divided into two equal doses and administered 8 to 12 hours apart (morning and night), orally or mixed with either dry or wet food, and (*b*) for prevention of heartworm disease at a dosage of 3 milligrams per pound of body weight daily, orally or in food, in heartworm endemic areas, from the beginning of mosquito activity, during the mosquito season, and for 2 months following the end thereof.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis*. Use of the drug is contraindicated in dogs with active *D. immitis* infections.

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 28265, July 9, 1976; 44 FR 3967, Jan. 19, 1979; 47 FR 14150, Apr. 2, 1982; 47 FR 35186, Aug. 13, 1982; 49 FR 33997, Aug. 28, 1984; 50 FR 41489, Oct. 11, 1985; 53 FR 47027, Oct. 18, 1988; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997]

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Specifications*. Each chewable tablet contains 30, 45, 60, 120, 150, or 180 milligrams of diethylcarbamazine citrate.

(b) *Sponsors*. See drug listing nos. in § 510.600(c) of this chapter for identification of sponsors as follows:

(1) For 015579, use of 30 or 120 milligram tablets as in paragraph (c)(2)(i) of this section.

(2) For 000069, use of 60, 120, or 180 milligram tablets as in paragraph (c)(2)(ii) of this section.

(3) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(iii) of this section.

(4) For 061133, use of 60-, 120-, or 180-milligram tablets as in paragraph (c)(2)(i) of this section.

(5) For 000061, use of 60-milligram tablets as in paragraph (c)(2)(i) of this section.

(6) For 000010, use of 30, 60, 120, or 180 milligram tablets as in paragraph (c)(2)(i) of this section.

(7) [Reserved]

(c) *Conditions of use*—(1) *Amount*. 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(2) *Indications for use*. (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats.

(ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.

(iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(3) *Limitations*. Tablets are administered orally or pulverized and given in the feed. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of

heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 6941, Feb. 17, 1978]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.622c, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.622d Diethylcarbamazine citrate capsules.

(a)(1) *Specifications*. Each capsule contains either 12.5, 50, 200, or 400 milligrams of diethylcarbamazine citrate.

(2) *Sponsor*. See 011014 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount/indications for use*. 3 milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs; 25 to 50 milligrams per pound of body weight in a single dose as an aid in the treatment of ascarid infections in dogs (*Toxocara canis* and *Toxascaris leonina*).

(ii) *Limitations*. Administer orally directly or added to the daily ration. For ascarid infections, repeat treatment in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion or shock. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. Each capsule contains either 12.5, 50, 200, or 400 milligrams of diethylcarbamazine citrate.

(2) *Sponsor*. See 023851 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount/indications for use*. 3 milligrams per pound of body weight daily for prevention of heartworm disease *(Dirofilaria immitis)* in dogs.

(ii) *Limitations*. Capsules may be administered to the dog directly or added to the daily ration. For oral administration only. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm infected dogs may cause adverse reactions due to pulmonary occlusion or shock. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 26377, June 18, 1982, as amended at 48 FR 46979, Oct. 17, 1983; 49 FR 5099, Feb. 10, 1984]

§ 520.623 Diethylcarbamazine citrate, oxibendazole chewable tablets.

(a) *Specifications*. Each tablet contains either 60, 120, or 180 milligrams of diethylcarbamazine citrate with 45, 91, or 136 milligrams of oxibendazole, respectively.

(b) *Sponsor*. See 000069 in §510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally to dogs at a dosage level of 6.6 milligrams of diethylcarbamazine citrate per kilogram of body weight (3 milligrams per pound of body weight) and 5.0 milligrams of oxibendazole per kilogram of body weight (2.27 milligrams per pound of body weight).

(2) *Indications for use*. For prevention of infection with *Dirofilaria immitis* (heartworm disease) and *Ancylostoma caninum* (hookworm infection) and for removal and control of *Trichuris vulpis* (whipworm infection) and mature and immature stages of intestinal *Toxocara canis* (ascarid infection).

(3) *Limitations*. Orally administer daily during heartworm season. For free-choice feeding or broken and placed on or mixed with feed. Do not use in dogs that may harbor adult heartworms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 28768, July 16, 1985, as amended at 53 FR 45759, Nov. 14, 1988; 54 FR 3776, Jan. 26, 1989; 54 FR 6804, Feb. 14, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.645 Difloxacin.

(a) *Specifications*. Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.6 mg/pound) of body weight.

(ii) *Indications for use*. For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations*. Use once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days. Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 8123, Feb. 18, 1998]

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) *Chemical name*. 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene) - 1,3 - pentadienyl]-benzothiazolium iodide.

(b) *Specifications*. Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

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

(d) *Conditions of use*. (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (*Toxocara canis, Toxascaris leonina*)	10	3–5
Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*)	10	7
Whipworms (*Trichuris vulpis*)	10	
Strongyloides (*Strongyloides canis, Strongyloides stercoralis*)	10	10–12
Heartworm microfilariae (*Dirofilaria immitus*)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763b Dithiazanine iodide powder.

(a) *Chemical name*. 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinylidene)-1,3-pentadienyl]-benzothiazoliumiodide.

(b) *Specifications*. Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

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

(d) *Conditions of use*. (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (*Toxocara canis, Toxascaris leonina*)	10	3–5

	Milligrams per pound of body weight	Length of treatment—days
Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*)	10	7
Whipworms (*Trichuris vulpis*)	10	7
Strongyloides (*Strongyloides canis, Strongyloides stercoralis*)	10	10–12
Heartworm microfilariae (*Dirofilaria immitus*)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

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

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

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Amount*. 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; ¾ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10¼ ounces to animals over 1,200 pounds.

(2) *Indications for use*. For control of large roundworms, *Parascaris equorum;* small strongyles; large strongyles, *Strongylus vulgaris;* and pinworms, *Oxyuris equi*.

(3) *Limitations*. Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.784 Doxylamine succinate tablets.

(a) *Specifications*. The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

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

(c) *Conditions of use*. (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.[1]

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses.[1]

(3) Not for use in horses intended for food.[1]

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

§ 520.804 Enalapril tablets.

(a) *Specifications*. Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.

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

(iii) *Limitations*. Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2-week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvular disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[59 FR 17694, Apr. 14, 1994, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.812 Enrofloxacin tablets.

(a) *Specifications*. Each tablet contains either 22.7, 68.0, or 136.0 milligrams of enrofloxacin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use*. Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations*. Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 3444, Jan. 24, 1989, as amended at 55 FR 43327, Oct. 29, 1990; 62 FR 38906, July 21, 1997; 64 FR 48295, Sept. 3, 1999]

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications*. Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

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

(c) *Related tolerances*. See § 556.228 of this chapter.

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

(1) *Chickens and turkeys*—(i) *Amount*. 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications*. Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations*. Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 56893, Nov. 5, 1996]

§ 520.816 Epsiprantel tablets.

(a) *Specifications*. Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 2.5 milligrams per pound of body weight.

(ii) *Indications for use*. Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(2) *Cats*—(i) *Amount*. 1.25 milligrams per pound of body weight.

(ii) *Indications for use*. Removal of feline cestodes *D. caninum* and *T. taeniaeformis*.

(3) *Limitations*. For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.823 Erythromycin phosphate.

(a) *Specifications*. Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor*. See No. 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.230 of this chapter.

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

(1) *Broiler and replacement chickens*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations*. Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(2) *Replacement chickens and chicken breeders*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of infectious coryza due to *Hemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations*. Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) *Growing turkeys*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations*. Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001]

§ 520.863 Ethylisobutrazine hydrochloride tablets.

(a) *Specifications*. Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

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

(c) *Conditions of use*. (1) It is administered orally to dogs as a tranquilizer.[1]

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.[1]

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.[1]

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.870 Etodolac.

(a) *Specifications*. Each tablet contains 150 or 300 milligrams (mg) of etodolac.

(b) *Sponsor*. See 053501 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 10 to 15 mg per kilogram (4.5 to 6.8 mg/pound) of body weight per day.

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

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

(2) [Reserved]

[63 FR 51300, Sept. 25, 1998]

§ 520.903 Febantel oral dosage forms.

§ 520.903a Febantel paste.

(a) *Chemical name*. Dimethyl [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl] carbonimidoyl]bis [carbamate].

(b) *Specifications*. The drug is a paste containing 45.5 percent febantel.

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

(d) *Conditions of use*—(1) *Amount*. Six milligrams per kilogram (2.73 milligrams per pound) of body weight in horses.

(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 the various small strongyles in horses, foals, and ponies.

(3) *Limitations*. (i) The paste may be administered on the base of the tongue or well mixed into a portion of the normal grain ration.

(ii) [Reserved]

(iii) 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.

(iv) Not for use in horses intended for food.

(v) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 8797, Mar. 3, 1978; 43 FR 12311, Mar. 24, 1978, as amended at 43 FR 60882, Dec. 29, 1978. Redesignated at 45 FR 8587, Feb. 8, 1980]

§ 520.903b Febantel suspension.

(a) *Specifications*. The suspension contains 9.3 percent (2.75 grams per ounce) febantel.

(b) *Sponsor*. See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight).

(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 the various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

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

(d) *Special considerations*. Febantel suspension may be used in combination with trichlorfon oral liquid in accordance with the provisions of § 520.2520c, this section, and the following conditions:

(1) Combine 1 part febantel suspension with 5 parts trichlorfon liquid.

(2) Allow animal to consume a portion of daily grain ration; administer mixture by stomach tube at rate of 18 milliliters per 100 pounds of body weight.

[45 FR 8587, Feb. 8, 1980]

§ 520.903c [Reserved]

§ 520.903d Febantel-praziquantel paste.

(a) *Specifications*. Each gram of paste contains 34 milligrams of febantel and 3.4 milligrams of praziquantel.

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

(c) *Conditions of use*—(1) *Amount*—(i) Dogs and cats (over 6 months of age): 10 milligrams of febantel and 1 milligram of praziquantel per kilogram of body weight (1 gram of paste per 7.5 pounds body weight) administered by mouth or in the food once daily for 3 days.

(ii) Puppies and kittens (less than 6 months of age): 15 milligrams of febantel and 1.5 milligrams of praziquantel per kilogram of body weight (1 gram of paste per 5 pounds body weight) administered by mouth on a full stomach once daily for 3 days.

(2) *Indications for use*. (i) Dogs and puppies: For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(ii) Cats and kittens: For removal of hookworms (*Ancylostoma tubaeforme*), ascarids (*Toxocara cati*) and tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*).

(3) *Limitations*. Do not use in pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction.

[50 FR 19167, May 7, 1985, as amended at 53 FR 48533, Dec. 1, 1988; 56 FR 50813, Oct. 9, 1991]

§ 520.903e Febantel tablets.

(a) *Specifications*. Each scored tablet contains 27.2 milligrams of febantel for use in dogs, puppies, cats, and kittens or 163.3 milligrams of febantel for use in dogs, puppies, and cats.

(b) *Sponsor*. See 000859 in § 510.600(c)(2) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats*. Ten milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(ii) *Puppies and kittens fewer than 6 months of age*. Fifteen milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(2) *Indications for use*. (i) For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*) and whipworms (*Trichuris vulpis*) in dogs and puppies.

(ii) For removal of hookworms (*Ancylostoma tubaeforme*) and ascarids (*Toxocara cati*) in cats and kittens.

(3) *Limitations*. Do not use in pregnant animals. Consider alternative therapy or use with caution in animals with preexisting liver or kidney dysfunction. Administer to puppies and kittens on a full stomach. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 50655, Oct. 8, 1991]

§ 520.905 Fenbendazole oral dosage forms.

§ 520.905a Fenbendazole suspension.

(a) *Specifications*. The drug is a suspension containing 10 percent (100 milligrams per milliliter) fenbendazole.

(b) *Sponsor*. See No. 012799 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.275 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram for the control of ascarids.

(ii) *Indications for use*. For the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles (*Cyanthostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Triodontophorus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

(iii) *Limitations*. Administer orally by dose syringe or suitable plastic syringe. Do not use in horses intended for food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Cattle including dairy cows of breeding age*—(i) *Amount*. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) *Indications for use*. For the removal and control of lungworm (*Dictyocaulus viviparus*); stomach worm (adults)—brown stomach worm (*Ostertagia ostertagi*); stomach worms (adults and 4th-stage larvae)—barberpole worm (*Haemonchus contortus*

and *H. placei*) and small stomach worm (*Trichostongylus axei*); intestinal worms (adults and 4th-stage larvae)—hookworm (*Bunostonmum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Beef cattle*—(i) *Amount*. Administer orally 10 milligrams per kilogram of body weight.

(ii) For the removal and control of stomach worm (4th-stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi*, and tapeworm, *Moniezia benedeni*.

(iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount*. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) *Indications for use*. For the removal and control of stomach and intestinal worms *Haemonchus contortus* and *Ostertagia circumcincta*.

(iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Goats must not be slaughtered for food within 6 days following last treatment. Do not use in lactating goats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Special considerations*. Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (d) of this section and for treating infections of stomach bot as provided in § 520.2520, have been shown to be compatible and not to interfere with one another.

[42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998]

§ 520.905b Fenbendazole granules.

(a) *Specifications*. The drug is in granular form containing 22 percent (222 milligrams per gram) fenbendazole.

(b) *Sponsor*. See No. 012799 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram for the control of ascarids.

(ii) *Indications for use*. For the control of infections of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*).

(iii) *Limitations*. Sprinkle the appropriate amount of drug on a small amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Dogs*—(i) *Amount*. 50 milligrams per kilogram (22.7 milligrams per pound) daily for 3 consecutive days.

(ii) *Indications for use*. For the removal of ascarids (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations*. Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Zoo and wildlife animals*—(i) *Amount*. Ten milligrams per kilogram per day for 3 days.

(ii) *Indications for use*. For control of internal parasites of *Felidae* and *Ursidae* as follows:

(A) Lion (*Panthera leo*) and Tiger (*Panthera tigris*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.).

(B) Cheetah (*Acinonyx jubatus*): Ascarid (*Toxocara cati*, *Toxascaris leonina*).

(C) Puma (*Felis concolor*), Panther (*Panthera* spp.), Leopard (*Panthera pardus*), Jaguar (*Panthera onca*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.), Tapeworm (*Taenia hydatigena*, *T. krabbei*, *T. taeniaeformis*).

(D) Black Bear (*Ursus americanus*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*), Hookworm (*Ancylostoma caninum*), Tapeworm (*Taenia hydatigena*, *T. krabbei*).

(E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*).

(iii) *Limitations*. Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994]

§ 520.905c Fenbendazole paste.

(a) *Specifications*. The product is an aqueous paste containing 10 percent fenbendazole.

(b) *Sponsor*. See No. 012799 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.275 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i)(*a*) *Amount*. 2.3 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 1,100-pound horse). For foals and weanlings (less than 18 months of age), 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for each 550 pounds of body weight).

(*b*) *Indications for use*. For control of large strongyles *(Strongylus edentatus, S. equinus, S. vulgaris)*, small strongyles, pinworms *(Oxyuris equi)*, and ascarids *(Parascaris equorum)* in horses.

(*c*) *Limitations*. Retreatment at intervals of 6 to 8 weeks may be required. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii)(*a*) *Amount*. 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 550-pound horse) daily for 5 days.

(*b*) *Indications for use*. For control of arteritis caused by the fourth stage larvae of *Strongylus vulgaris*.

(*c*) *Limitations*. Treatment should be initiated in the spring and repeated in 6 months. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of fourth stage larvae of *S. vulgaris*.

(iii)(*a*) *Amount*. 4.6 milligrams per pound of body weight (10 milligrams per kilogram) daily for 5 consecutive days.

(*b*) *Indications for use*. For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae in horses.

(*c*) *Limitations*. (Consult your veterinarian for assistance in the diagnosis, treatment, and control of encysted mucosal cyathostomes). Do not use in horses intended for food.

(2) *Beef and dairy cattle*—(i) *Amount*. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) *Indications for use*. For the removal and control of lungworm (*Dictyocaulus viviparus*), barberpole worm (*Haemonchus contortus*), brown stomach worm (*Ostertagia ostertagi*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), thread-necked intestinal worm (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(iii) *Limitations*. Re-treatment may be needed after 4 to 6 weeks. Cattle must

not be slaughtered within 8 days following last treatment. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(e) *Special considerations.* Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (d)(1)(i) of this section and for treating infections of stomach bots as provided in § 520.2520.

[46 FR 32018, June 19, 1981, as amended at 47 FR 15327, Apr. 9, 1982; 49 FR 8433, Mar. 7, 1984; 50 FR 26358, June 26, 1985; 61 FR 29478, June 11, 1996; 63 FR 31624, June 10, 1998]

§ 520.905d Fenbendazole powder.

(a) *Specifications.* (1) Each 2-ounce packet contains 2.27 grams (4 percent) of fenbendazole plus other inert ingredients.

(2) Each 4-ounce packet contains 1.7 grams (1.5 percent) of fenbendazole plus other inert ingredients.

(b) *Sponsors.* (1) See No. 012799 in § 510.600(c) of this chapter for use of the 4-percent product.

(2) See No. 017800 in § 510.600(c) of this chapter for use of the 1.5-percent product.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use.* It is administered to swine as follows:

(1) *Amount.* 3 milligrams fenbendazole per kilogram body weight per day (1.36 milligrams per pound per day).

(2) *Indications for use.* For removal and control of large roundworms (*Ascaris suum)*; lungworms (*Metastrongylus apri)*; nodular worms *(Oesophagostomum dentatum, O. quadrispinulatum)*; small stomach worms *(Hyostrongylus rubidus)*; whipworms *(Trichuris suis*); and kidneyworms *(Stephanurus dentatus*—mature and immature).

(3) *Limitations.* Thoroughly mix the contents of the packet(s) with swine ration and administer according to label directions. Feed as sole ration for 3 consecutive days. Can be fed to pregnant sows. No prior withdrawal of feed or water is necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 18090, Apr. 27, 1984, as amended at 49 FR 20485, May 15, 1984]

§ 520.905e Fenbendazole blocks.

(a) *Specifications.* (1) Each pound of molasses block contains 750 milligrams of fenbendazole.

(2) Each pound of protein block contains 750 milligrams of fenbendazole.

(b) *Sponsor.* See 012799 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 0.1 pound of block per 100 pounds of body weight per day for 3 days. Total dose for the 3-day period is 2.27 milligrams of fenbendazole per pound of body weight for mature cattle.

(2) *Indications for use.* For removal and control of infections of lungworms *(Dictyocaulus viviparus)* and gastrointestinal roundworms *(Haemonchus contortus, Ostertagia ostertagi, Trichostrongylus axei, Bunostomum phlebotomum, Nematodirus helvetianus, Cooperia oncophora* and *C. punctata, Trichostrongylus colubriformis,* and *Oesophagostomum radiatum)* in beef cattle.

(3) *Limitations.* Administer free choice of beef cattle on pasture that have become accustomed to nonmedicated block feeding during an adaptation period of 12 to 19 days. Molasses block: Cattle must not be slaughtered within 11 days following last treatment. Protein block: Cattle must not be slaughtered within 16 days following last treatment; do not use in dairy cattle of breeding age. Animals maintained under conditions of constant worm exposure may require retreatment within 6 to 8 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 41783, Nov. 19, 1986, as amended at 54 FR 20787, May 15, 1989]

§ 520.960 Flumethasone tablets.

(a) *Specifications.* Each tablet contains 0.0625 milligram of flumethasone.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. (i) *Dogs:* Administer orally from 0.0625 to 0.25 milligram daily in divided doses.

(ii) *Cats:* Administer orally from 0.03125 to 0.125 milligram daily in divided doses.

(2) *Indications for use*. (i) *Dogs:* It is used for musculoskeletal conditions due to inflammation of muscles or joints and accessory structures, where permanent structural changes do not exist, such as arthritis, the disc syndrome, and myositis.

(ii) *Dogs and cats:* It is used in certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations*. Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infection. Do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or where peptic ulcers occur, except for emergency therapy. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 7131, Feb. 6, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

§ 520.970 Flunixin oral dosage forms.

§ 520.970a Flunixin meglumine granules.

(a) *Specifications*. Each 10-gram packet contains flunixin meglumine equivalent to 250 milligrams of flunixin.

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

(c) *Conditions of use*—(1) *Amount*. 0.5 milligram of flunixin per pound of body weight (one packet per 500 pounds) per day.

(2) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

(3) *Limitations*. Administer daily dose for up to 5 days by sprinkling on small amount of feed. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 36381, June 22, 1979. Redesignated at 50 FR 38114, Sept. 20, 1985, and amended at 52 FR 7832, Mar. 13, 1987]

§ 520.970b Flunixin meglumine paste.

(a) *Specifications*. Each 30-gram syringe contains flunixin meglumine equivalent to 1,500 milligrams of flunixin.

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

(c) *Conditions of use*. *Horses*—(1) *Amount*. 0.5 milligram of flunixin per pound of body weight daily.

(2) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders.

(3) *Limitations*. For oral use only. Treatment should not exceed 5 consecutive days. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 38114, Sept. 20, 1985, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.1010 Furosemide oral dosage forms.

§ 520.1010a Furosemide tablets or boluses.

(a) *Specifications*. Each tablet contains 12.5 or 50 milligrams of furosemide. Each bolus contains 2 grams of furosemide.

(b) *Sponsor*. See No. 012799 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (c) (1) and (2) of this section; see No. 000010 in § 510.600(c) of this chapter for use in dogs as provided for in paragraph (c)(1) of this section; see No. 000093 in § 510.600(c) of this chapter for use of a 12.5- and 50-milligram tablet for conditions of use provided for in paragraph (c)(3) of this section.

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

(1) *Dogs and cats*—(i) *Amount*. 1 to 2 milligrams per pound of body weight, once or twice daily, with a 6- to 8-hour

interval between successive daily doses.

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

(iii) *Limitations.* The dosage should be adjusted to the animal's response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema, or when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. The drug, if given in excessive amounts or over extended periods of time may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 1 to 2 milligrams per pound of body weight, or one 2-gram bolus per animal, per day.

(ii) *Indications for use.* The drug is used for the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. For oral use only. When treatment is initiated with an injectable, it is followed by a 12-hour interval, and maintained by oral administration. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment. The drug, if given in excessive amounts or over extended periods of time, may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs*—(i) *Amount.* 1 to 2 milligrams per pound of body weight, once or twice daily, with a 6- to 8-hour interval between successive daily doses.

(ii) *Indications for use.* It is used for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(iii) *Limitations.* The dosage should be adjusted to the animal's response. In severe cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema, or when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. The drug, if given in excessive amounts or over extended periods of time, may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 52446, Nov. 30, 1976. Redesignated at 43 FR 14647, Apr. 7, 1978, and amended at 48 FR 40517, Sept. 8, 1983; 48 FR 49841, Oct. 28, 1983; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 6724, Feb. 13, 1997; 62 FR 35076, June 30, 1997]

§ 520.1010b Furosemide powder.

(a) *Specifications.* Furosemide powder is packaged in packets containing 2 grams of furosemide plus other inert ingredients.

(b) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is administered to dairy cattle alone, as a ''top dressing'' upon a small amount of feed or as a drench.

(1) *Amount.* 1 to 2 milligrams per pound of body weight but not to exceed one packet per animal, per day.

(2) *Indications for use.* The drug is used for the treatment of physiological parturient edema of the mammary gland and associated structures.

(3) *Limitations.* Treatment not to exceed 48 hours post-parturition. For oral use only. The individual dose is one packet administered once daily; when treatment is initiated with an injectable, at least a 12-hour interval must follow before oral administration. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment. The drug, if given in excessive amounts or over extended periods of time, may result in dehydration and

electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 14647, Apr. 7, 1978, as amended at 47 FR 15327, Apr. 9, 1982]

§ 520.1010c Furosemide syrup.

(a) *Specifications*. Each milliliter of syrup contains 10 milligrams of furosemide.

(b) *Sponsor*. See. No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 1 to 2 milliliters orally (10 to 20 milligrams) per 10 pounds of body weight (approximately 2.5 to 5 milligrams per kilogram), once or twice daily, with a 6- to 8-hour interval between sucessive daily doses.

(2) *Indications for use*. It is used in dogs for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(3) *Limitations*. The dosage should be adjusted to the animal's response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema or, when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. If given in excessive amounts or over extended periods of time, the drug may result in dehydration and/or eletrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 11177, Mar. 17, 1978, as amended at 47 FR 15327, Apr. 9, 1982]

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications*. Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) *Sponsor*. See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount*. Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use*. In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations*. For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 3 days following treatment.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997]

§ 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications*. Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsor*. See Nos. 000061 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount*. Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use*. In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations*. For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997]

§ 520.1044c Gentamicin sulfate soluble powder.

(a) *Specifications.* Each gram of gentamicin sulfate soluble powder contains gentamicin sulfate equivalent to 16.7, 66.7, or 333.3 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: gentamicin sulfate equivalent to 25 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 0.5 milligram per pound of body weight per day; swine dysentery: gentamicin sulfate equivalent to 50 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 1 milligram per pound of body weight per day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 10 days following treatment.

[49 FR 29778, July 24, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 48675, Dec. 24, 1987; 62 FR 29013, May 29, 1997]

§ 520.1100 Griseofulvin.

(a) *Chemical name.* 7-Chloro-2′,4,6-trimethoxy-6′-methylspiro [benzofuran-2(3H), 1′-[2]-cyclohexene]-3,4′-dione.

(b) *Specifications.* Complies with U.S.P. for griseofulvin microsize.

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

(d) *Conditions of use.* (1) As a soluble powder for horses, it is administered as a drench or as a top dressing on feed. It is used for equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum.* Administer for not less than 10 days a daily dose as follows: Adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

(2)(i) Boluses containing 2.5 grams of griseofulvin are used in horses for treating ringworm infection caused by *Trichophyton equinum.* It is administered to adult horses at a level of one bolus per day, to yearlings at one-half to one bolus per day, and to foals at one-half bolus per day. All three dosage levels should be administered for a period of not less than 10 days. In responsive cases, treatment should be continued until all infected areas are proven negative by appropriate culture. Not for use in horses intended for food.

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

(3) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(*a*) Daily (single or divided) dose:

Body weight (pounds)	Dosage (milligrams)
Up to 6	62.5
6 to 18	125
18 to 36	250
36 to 48	375
48 to 75	500

(*b*) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight x body weight x number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes, T. rubrum, T. schoenleini, T. sulphurem, T. verrucosum, T. interdigitale, Epidermophyton floccosum, Microsporum gypseum, M. canis, M. audouini.*

(iii) *Limitations.* For satisfactory diagnosis, a microscopic tissue examination or culture is recommended prior to treatment. Treatment should be continued for 3 to 4 weeks in skin and

hair infections, and up to 4 months for infections involving nails or claws. Clipping of hair, nails, and claws to help remove any remaining viable fungi is indicated. Safety for use of griseofulvin for pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Chemical name*. 3-Choloro-7-hydoxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications*. Haloxon assay of not less than 96 percent by infrared spectrum at 8.62 microns.

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

(d) *Special considerations*. Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(e) *Related tolerances*. See § 556.310 of this chapter.

(f) *Conditions of use*. It is used as a drench as follows:

(1) *Cattle* —(i) *Amount*. 141.5 grams per packet.

(ii) *Indications for use*. Control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(iii) *Limitations*. (*a*) Dissolve each packet in 32 fluid ounces of water and administer as follows:

Weight of animal (pounds)	Dose (fluid ounces)
Up to 100	½
100 to 150	¾
150 to 200	1
200 to 300	1½
300 to 450	2
450 to 700	3
700 to 1,000	4
1,000 to 1,200	5
Over 1,200	6

(*b*) Do not treat within 1 week of slaughter; do not treat dairy animals of breeding age; animals should be retreated in 3 to 4 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.1120b Haloxon boluses.

(a) *Chemical name*. 3-Chloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications*. Each bolus contains 10.1 grams of haloxon.

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

(d) *Related tolerances*. See § 556.310 of this chapter.

(e) *Conditions of use*. (1) Haloxon bolus is an anthelmintic used in cattle for the control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus* and *Cooperia*.

(2) It is administered by giving one bolus per approximately 500 pounds body weight (35 to 50 milligrams per kilogram of body weight).

(3) For most effective results, retreat animals in 3 to 4 weeks. If reinfection is likely to occur, additional retreatments may be necessary.

(4) Do not use any drug, pesticide or other chemical having cholinesterase inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(5) Do not treat animals within one week of slaughter.

(6) Do not treat dairy animals of breeding age or older.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 61591, Oct. 29, 1979; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.1130 Hetacillin oral dosage forms.

§ 520.1130a Hetacillin potassium capsules.

(a) *Specifications*. Each capsule contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body

weight, twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals raised for food production. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 50 milligrams twice daily.

(ii) *Indications for use.* Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(3) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer in a fasting state to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals raised for food production. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992]

§ 520.1130b Hetacillin potassium oral suspension.

(a) *Specifications.* Each milliliter contains hetacillin potassium equivalent to 50 milligrams of ampicillin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 milligrams per pound of body weight twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft-tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in dogs only. Not for use in animals raised for food production. Continue treatment 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 50 milligrams twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft-tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in cats only. Not for use in animals raised for food production. Continue treatment 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992]

§ 520.1130c Hetacillin potassium tablets.

(a) *Specifications.* Each tablet contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 milligrams per pound of body weight twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract

infections, up to 20 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Oral treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 50 milligrams twice daily.

(ii) *Indications for use.* Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992]

§ 520.1157 Iodinated casein tablets.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* ⅕ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 22469, May 30, 1984]

§ 520.1158 Iodochlorhydroxyquin boluses.

(a) *Specifications.* Each bolus contains 10 grams of iodochlorhydroxyquin.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 1 bolus (10 grams) daily for a 1,000-pound horse.

(2) *Indications for use.* For treatment of equine diarrhea.

(3) *Limitations.* For horses only; not to be administered to food-producing animals. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 8054, Feb. 25, 1983, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.1182 Iron dextran oral suspension.

(a) *Specifications.* Each 1.8 milliliter contains 100 milligrams of elemental iron as ferric hydroxide in complex with a low molecular weight dextran and 0.2 percent phenol as a preservative.

(b) *Sponsor.* See 017800 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 100 milligrams of elemental iron to each pig.

(2) *Indications for use.* Prevention of iron deficiency anemia in baby pigs.

(3) *Limitations.* Treat each pig within 24 hours of farrowing. Administer 1.8 milliliters orally by automatic dose dispenser.

[45 FR 75199, Nov. 14, 1980]

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram of paste contains 0.0187 milligram (1.87 percent) or 0.00153 milligram (0.153 percent) of ivermectin.

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

(1) No. 050604 for use of a 1.87 percent paste as in paragraph (d)(1) of this section and a 0.153 percent paste as in paragraph (d)(2) of this section.

(2) No. 059130 for use of a 1.87 percent paste as in paragraph (d)(1) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use*. It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*), (adult) (*Triodontophorus* spp.); small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); pinworms (adult and fourth stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); large mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(iii) *Limitations*. For oral use only. Do not use in horses intended for food purposes. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Cattle*—(i) *Amount*. 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use*. It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); and sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*).

(iii) *Limitations*. For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000]

§ 520.1193 Ivermectin tablets and chewables.

(a) *Specifications*—(1) *Dogs*. Each tablet or chewable contains 68, 136, or 272 micrograms of ivermectin.

(2) *Cats*. Each chewable contains 55 or 165 micrograms of ivermectin.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 6.0 micrograms per kilogram body weight (2.72 micrograms per pound), minimum. For dogs up to 25 pounds, 68 micrograms; dogs 26 to 50 pounds, 136 micrograms; dogs 51 to 100 pounds, 272 micrograms; dogs over 100 pounds, a combination of the appropriate tablets. The drug is administered at monthly dosing intervals.

(2) *Indications for use*. To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(3) *Limitations*. Use once-a-month. Recommended for dogs 6 weeks of age and older. Initial use within 1 month after first exposure to mosquitoes. Final use within 1 month after last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use in cats*—(1) *Amount*. Up to 2.3 kilograms (up to 5 pounds), 55 micrograms; 2.3 to 6.8 kilograms (5 to 15 pounds), 165 micrograms;

over 6.8 kilograms (15 pounds), a combination of the appropriate chewables (recommended minimum dose of 24 micrograms of ivermectin per kilogram of body weight (10.9 micrograms per pound).

(2) *Indications for use*. To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

(3) *Limitations*. For use in cats 6 weeks of age and older. Administer once a month. The initial dose must be given within a month after cats first exposure to mosquitoes. The final dose must be given within a month after the cats last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 11042, Apr. 7, 1987, as amended at 54 FR 32337, Aug. 7, 1989; 61 FR 39868, July 31, 1996; 62 FR 5319, Feb. 5, 1997; 62 FR 63270, Nov. 28, 1997]

§ 520.1194 Ivermectin drench.

(a) *Specifications*. Each milliliter of 0.08 percent (weight per volume) micellar solution contains 0.08 milligram of ivermectin.

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

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Conditions of use*—(1) *Amount*. 3.0 milliliters (2.4 milligrams of ivermectin) per 26 pounds of body weight (or 200 micrograms per kilogram of body weight).

(2) *Indications for use*. It is used in sheep for treatment and control of the adult and fourth-stage larvae of the following parasites of sheep: gastrointestinal roundworms (*Haemonchus contortus*, *H. placei* (adults only), *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. Colubriformis*, *Cooperia oncophora* (adults only), *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults only), *Nematodirus battus*, *N. spathiger*, *Strongyloides papillosus* (adults only), *Chabertia ovina* (adults only), *Trichuris ovis* (adults only)), lungworms (*Dictyocaulus filaria*); and all larval stages of the nasal bot *Oestrus ovis*.

(3) *Limitations*. It is used as a drench in sheep only. Do not treat sheep within 11 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 27958, July 26, 1988, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.1195 Ivermectin liquid.

(a) *Specifications*. Each milliliter contains 10 milligrams of ivermectin.

(b) *Sponsor*. See Nos. 050604, 051259, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 200 micrograms per kilogram of body weight as a single dose.

(2) *Indications for use*. It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus endentatus*), (adult) (*Triodontophorus* spp.); small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); pinworms (adult and fourth stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostongylus axei*); large mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(3) *Limitations*. Administer by stomach tube or as an oral drench. Do not use in horses intended for food purposes. Federal law restricts this drug to us by or on the order of a licensed veterinarian.

[52 FR 34637, Sept. 14, 1987, as amended at 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 63 FR 38474, July 17, 1998; 66 FR 7579, Jan. 24, 2001]

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablet.

(a) *Specifications*. Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg and 114 mg, or 272 µg and 227 mg, respectively.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. A minimum of 6 µg of ivermectin and 5 mg of pyrantel (as pamoate salt) per kilogram (2.72 µg and 2.27 mg per pound) of body weight.

(ii) *Indications for use*. To prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for up to a month (30 days) after infection and treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina*, and adult hookworms *Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*.

(iii) *Limitations*. Use monthly. Recommended for dogs 6 weeks of age and older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997]

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications*. Each sustained-release bolus contains 1.72 grams of ivermectin.

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

(c) *Related tolerances. See § 556.344 of this chapter*.

(d) *Conditions of use in ruminating calves*—(1) *Amount*. Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications*. For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms *Haemonchus placei*, *Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum;* lungworms *Dictyocaulus viviparus;* grubs *Hypoderma* spp.; sucking lice *Linognathus vituli*, *Solenopotes capillatus;* mange mites *Psoroptes ovis*, *Sarcoptes scabiei*, and ticks *Amblyomma americanum*.

(3) *Limitations*. The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000]

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.

(a) *Specifications*. Each five milliliters of suspension of the drug contains: 100 milligrams of kanamycin as the sulfate, 0.033 milligram of aminopentamide hydrogen sulfate, 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is administered orally to dogs for the symptomatic relief of acute bacterial diarrhea caused by kanamycin-susceptible organisms.

(2) The drug is recommended for use at the rate of one teaspoonful (5 milliliters) of suspension per 20 pounds of body weight every 8 hours. Animals weighing under 10 pounds should be given one-half the above amount every 8 hours. The initial dose should be twice the amount of a single dose. Maximum dosage should not exceed three times the recommended dose.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999]

§ 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgite tablets.

(a) *Specifications*. Each tablet contains 100 milligrams of kanamycin (as the sulfate), 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. One tablet per 44 kilograms (20 pounds) of body weight every 8 hours. Maximum dose 3 tablets every 8 hours. For animals under 22 kilograms (10 pounds) ½ tablet every 8 hours. The initial loading dose should be twice the amount of a single dose.

(2)*Indications for use*. For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of associated diarrhea in dogs.

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

[56 FR 8710, Mar. 1, 1991]

§ 520.1242 Levamisole hydrochloride oral dosage forms.

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) *Specifications*. Each package contains either 9.075, 11.7, 18.15, 46.8, or 544.5 grams of levamisole hydrochloride.

(b) *Sponsors*. Approval for sponsors in 21 CFR 510.600(c) for use as in paragraph (d) of this section as follows:

(1) See 043781 for use of 46.8 gram package as in paragraph (d)(1) of this section, for 11.7 and 46.8 gram packages as in paragraph (d)(2) of this section, and for 9.075 and 18.15 gram packages as in paragraph (d)(3) of this section.

(2) See 000061 for use of 46.8 and 544.5 gram packages as in paragraph (d)(1) of this section, for 11.7, 46.8, and 544.5 gram packages as in paragraph (d)(2) of this section, and for 18.15 gram package as in paragraph (d)(3) of this section.

(3) See 057561 for use of 46.8 and 544.5 gram packages as in paragraphs (d)(1) and (d)(2) of this section.

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

(d) *Conditions of use*. It is used as an anthelmintic at 0.365 gram per 100 pounds of body weight as follows:

(1) *Cattle*—(i) *Amount*. As a single oral dose drench using 46.8 or 544.5 gram packet.

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

(iii) *Limitations*. Conditions of constant helminth exposure may require retreatment 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 your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 46.8 gram package in water to provide 1 quart (32 fluid ounces) of drench solution and administer as a drench at 1/4 ounce per 100 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in water to provide 8.75 fluid ounces of concentrate solution and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose by syringe.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(2) *Sheep*—(i) *Amount*. As a single oral dose drench using 11.7, 46.8, or 544.5 gram packet.

(*a*) *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*).

(*b*) *Limitations*. Dissolve in 1 gallon (128 fluid ounces) of water and administer as a single drench at 1 ounce (0.365

gram) per 100 pounds of body weight; 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 veterinarian before using in severely debilitated animals.

(ii) *Amount*. 11.7 grams per packet.

(*a*) *Indications for use*. See paragraph (f)(2)(i)(*a*) of this section.

(*b*) *Limitations*. Dissolve in 1 quart (32 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight or dissolve 1 packet in 10.9 fluid ounces of water and administer as a single drench at 1 cubic centimeter (0.036 gram) per 10 pounds of body weight; 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 veterinarian before using in severely debilitated animals.

(iii) *Limitations*. Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 11.7 gram package in 1 quart (32 ounces) of water and administer as a drench at 1 ounce per 100 pounds of body weight, or dissolve in 10.9 fluid ounces of water and administer as a drench at 1 milliliter per 10 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in 128 fluid ounces (1 gallon) of water and administer as a drench at 1 ounce per 100 pounds of body weight as a single oral dose.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(3) *Swine*—(i) *Amount*. 9.075 or 18.15 grams per bottle.

(ii) *Indications for use*. Anthelmintic effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(iii) *Limitations*. Dissolve in water to provide 9.075 grams per 250 milliliters or 18.15 grams per 500 milliliters. Add 10 milliliters (2 teaspoons) of this concentrate solution to each gallon of drinking water. Allow 1 gallon of medicated drinking water for each 100 pounds of body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 44 FR 59508, Oct. 16, 1979; 44 FR 72586, Dec. 14, 1979; 46 FR 25085, May 5, 1981; 52 FR 20598, June 2, 1987; 54 FR 18280, Apr. 28, 1989; 62 FR 61625, Nov. 19, 1997; 63 FR 59713, Nov. 5, 1998]

§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

(a) *Chemical name*. (-)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-*b*] thiazole monohydrochloride.

(b) *Specifications*. Assay of not less than 98 percent by nonaqueous titration with 0.1 *N* potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Sponsor*. See Nos. 000061 and 043781 in § 510.600(c) of this chapter.

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

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

(f) *Conditions of use*. (1) It is used in an oblet for cattle as follows:

(i) *Amount*. 2.19 grams per oblet.

(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*. Administer as a single dose as follows: 250 to 450 pounds, ½ oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, 1½ oblets; 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) It is used in a tablet for sheep as follows:

(i) *Amount*. 0.184 gram per tablet.

(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*. Administer one tablet for each 50 pounds of body weight; 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.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 59507, Oct. 16, 1979; 62 FR 61625, Nov. 19, 1997]

§ 520.1242c Levamisole hydrochloride and piperazine dihydrochloride.

(a) *Specifications*. (1) The drug is an aqueous solution which contains in each fluid ounce 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) The drug is a soluble powder which when reconstituted 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. 043781 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*. It is used as a drench for horses as follows:

(1) *Indications for use*. An anthelmintic effective against infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*), small strongyles (*Cylicocercus spp.*, *Cylicocylclus spp.*, *Cylicodontophorus spp.*, *Cylicostephanus spp.*, *Cylicotetrapedon spp.*), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equii*).

(2) *Limitations*. 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. Do not treat animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 32831, Aug. 5, 1975, as amended at 41 FR 48731, Nov. 5, 1976; 43 FR 11176 Mar. 17, 1978]

§ 520.1242d Levamisole resinate.

(a) *Specifications*. The drug is levamisole adsorbed on a resin, in a concentration equivalent to 10 percent levamisole hydrochloride. Each 2.05-ounce (58.1 gram) packet contains levamisole equivalent to 5.806 grams of levamisole hydrochloride.

(b) *Sponsor*. See No. 043781 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*. In swine it is used as follows:

(1) *Amount*. The equivalent of 8 milligrams per kilogram of body weight, as a single dose, mixed in the animal's ration.

(2) *Indications for use*. For the removal of and control of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and swine kidney worms (*Stephanurus dentatum*).

(3) *Limitations*. For pigs from weaning to market weight, mix one 58.1-gram packet of levamisole resinate containing the equivalent of 10-percent levamisole hydrochloride in 40 pounds

of feed and administer 1 pound of medicated feed per 40 pounds of body weight as sole ration. For breeding swine, mix 1 packet of the 10-percent resinate in 16 pounds of feed and administer 1 pound of medicated feed per 100 pounds of body weight as sole ration. Administer as single doses. Withhold regular feed overnight and administer medicated feed the following morning. Do not withhold water during fasting. Do not treat within 72 hours of slaughter. Salivation or muzzle foam may be observed. The reaction will disappear a short time after feeding. If pigs are infected with mature lungworms, coughing and vomiting may be observed. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 18171, Apr. 28, 1978, as amended at 45 FR 3574, Jan. 18, 1980]

§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) *Specifications*. Each tablet contains 907 milligrams of levamisole hydrochloride.

(b) *Sponsor*. See No. 043781 in § 510.600(c) of this chapter.

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

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

(1) *Amount*. The equivalent of 8 milligrams of levamisole hydrochloride per kilogram of body weight, as a single dose.

(2) *Indications for use*. See § 520.1242a(f)(3)(ii).

(3) *Limitations*. Withholding water from pigs before treatment is not necessary. Add one tablet for each 2½ gallons of water; mix thoroughly. Allow 1 gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[45 FR 6087, Jan. 25, 1980]

§ 520.1242f Levamisole hydrochloride gel.

(a) *Specifications*. The drug is a gel containing 11.5 percent levamisole hydrochloride.

(b) *Sponsor*. See No. 043781 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. Eight milligrams of levamisole hydrochloride per kilogram of body weight, as a single oral dose.

(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 administer to cattle within 6 days of slaughter for food; do not administer to dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) *Breeding swine*—(i) *Amount*. Eight milligrams per kilogram of body weight (3.6 milligrams per pound) as a single oral dose.

(ii) *Conditions of use*. For treating breeding swine infected with the following nematodes: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and kidney worms (*Stephanurus dentatus*).

(iii) *Limitations*. May require retreatment in 4 to 5 weeks. Do not use within 11 days of slaughter for food. Consult your veterinarian for assistance before using in severely debilitated animals and in the diagnosis, treatment, and control of parasitism.

[47 FR 22517, May 25, 1982; 47 FR 30242, July 13, 1982, as amended at 48 FR 11429, Mar. 18, 1983; 51 FR 29215, Aug. 15, 1986]

§ 520.1242g Levamisole resinate and famphur paste.

(a) *Chemical name of famphur*. *O, O*-Dimethyl *O*-[*p*-(dimethylsulfamoyl) phenyl] phosphorothioate.

(b) *Specifications*. The drug is a paste containing 11.6 percent levamisole resinate (50 percent potency) and 23.6 percent famphur.

(c) *Sponsor*. See 000061 in § 510.600(c) of this chapter.

(d) *Special considerations*. Do not use any cholinesterase-inhibiting drugs, pesticides, insecticides, or chemicals on cattle simultaneously or within a few days before or after treatment with this product.

(e) *Related tolerances*. See § 556.350 of this chapter for levamisole and § 556.273 of this chapter for famphur.

(f) *Conditions of use in cattle*—(1) *Amount*. 8 milligrams of levamisole hydrochloride (equivalent) and 30 milligrams of famphur activity per kilogram of body weight.

(2) *Indications for use*. For treatment of cattle infected with the following parasites: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), lungworms (*Dictyocaulus*), cattle grubs (*Hypoderma*), biting lice (*Bovicola*), and sucking lice (*Linognathus*, *Solenoptes*).

(3) *Limitations*. Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54 FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992; 62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997]

§ 520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.

§ 520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.

(a) *Specifications*. The sirup contains lincomycin hydrochloride equivalent to either 25 milligrams or 50 milligrams of lincomycin.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated in infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

(2) It is administered orally to dogs and cats at a dosage level of 10 mgs per pound of body weight every 12 hours, or 7 mgs per pound of body weight every 8 hours. Treatment may be continued for periods as long as 12 days if clinical judgment indicates.

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

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 64 FR 403, Jan. 5, 1999]

§ 520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.

(a) *Specifications*. The spectinomycin sulfate tetrahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces spectabilis* or the same antibiotic substance produced by any other means. The quantity of total antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drugs. Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate are present in the drug in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.600 and 556.360 of this chapter.

(d) *Conditions of use*. (1) It is administered in the drinking water of chickens

up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 1891, Jan. 13, 1976; 64 FR 403, Jan. 5, 1999]

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications*. Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin. The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) *Sponsors*. Approval for use of 40- and 80-gram packet to Nos. 000009 and 046573 in § 510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in § 510.600(c) of this chapter. Approval for use of 40-gram packet to No. 046573 § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.360 of this chapter.

(d) *Conditions of use*—(1) It is used in drinking water for swine as follows:

(i) *Amount*. 250 milligrams per gallon.

(A) *Dosage*. 3.8 milligrams per pound of body weight per day.

(B) *Indications for use*. Treatment of swine dysentery (bloody scours).

(C) *Limitations*. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. Not for use in swine weighing more than 250 pounds.

(ii) [Reserved]

(2) It is used in drinking water for broiler chickens as follows:

(i) *Amount*. 64 milligrams per gallon.

(A) *Indications for use*. For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

(B) *Limitations*. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

(ii) [Reserved]

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000]

§ 520.1284 Sodium liothyronine tablets.

(a) *Specifications*. Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram 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 (12.8μg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

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

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron.

(2) *Cats*. Each tablet contains either 90, 135, 204.9 or 270 mg of lufenuron.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Minimum of 10 mg of lufenuron per kilogram (4.5 mg per pound (lb)) of body weight.

(2) *Indications for use*. For use in dogs and puppies, 6 weeks of age and older, for the prevention and control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

(d) *Conditions of use in cats*—(1) *Amount*. Minimum of 30 mg of lufenuron per kilogram (13.6 mg/lb) of body weight.

(2) *Indications for use*. For use in cats and kittens, 6 weeks of age and older, for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

[63 FR 52968, Oct. 2, 1998]

§ 520.1289 Lufenuron suspension.

(a) *Specifications*. Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use*. For control of flea populations.

(3) *Limitations*. For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

[60 FR 20402, Apr. 26, 1995, as amended at 62 FR 8371, Feb. 25, 1997]

§ 520.1310 Marbofloxacin tablets.

(a) *Specifications*. Each tablet contains either 25, 50, 100, or 200 milligrams of marbofloxacin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 1.25 milligrams per pound of body weight once daily, but may be increased to 2.5 milligrams per pound of body weight once daily.

(ii) *Indications for use*. For the treatment of infections in dogs associated with bacteria susceptible to marbofloxacin.

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

[64 FR 39919, July 23, 1999]

§ 520.1320 Mebendazole oral.

(a) *Chemical name*. Methyl 5-benzoylbenzimindazole-2-carbamate.

(b) *Specifications*. As oral powder: Each gram contains either 40 or 166.7 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. As oral suspension: Each milliliter contains 33.3 milligrams of mebendazole.

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

(d) *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*. It is used in horses 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*—(*a*) *Oral powder*. The drug is given by sprinkling directly on the grain portion of the ration or dissolving in 2 to 4 pints of water and administering by stomach tube. The drug is compatible with carbon disulfide, which can be used concurrently for both control (*Gastrophilus spp.*). Routine cautions regarding the use of carbon disulfide must be observed. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(*b*) *Oral paste*. The drug is given by dosing gun (syringe), inserting the tip of the gun at the interdental space in the horse's mouth and depositing the paste on the animal's tongue. The hand is placed under the animal's jaw, and the head is raised to assure that the paste is deposited on the roof of the mouth. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(c) Oral suspension. The drug is administered by stomach tube. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount*. One hundred milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder.

(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*. Administer as an oral powder by mixing with a small quantity of food, preferably before the regular meal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 61255, Dec. 2, 1977, as amended at 43 FR 35686, Aug. 11, 1978; 45 FR 3574, Jan. 18, 1980; 46 FR 47218, Sept. 25, 1981; 46 FR 53658, Oct. 30, 1981; 62 FR 61625, Nov. 19, 1997]

§ 520.1326 Mebendazole and trichlorfon oral dosage forms.

§ 520.1326a Mebendazole and trichlorfon powder.

(a) *Specifications*. Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorofon.

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

(c) *Conditions of use*. *Horses*—(1) *Amount*. 8.8 milligrams of mebendazole and 40 milligrams of trichlorofon per kilogram of body weight.

(2) *Indications for use*. It is used in horses for the treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*.)

(3) *Limitations*. Administer orally as an individual dose by stomach tube or throughly mixed in the ground grain portion of the ration to be consumed in one feeding. Discard treated feed not consumed. Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorofon is a cholinesterase inhibitor. Do not administer simultaneously or within a few days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 10759, Feb. 19, 1980, as amended at 46 FR 52330, Oct. 27, 1981. Redesignated at 51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997]

§ 520.1326b Mebendazole and trichlorfon paste.

(a) *Specifications*. Each gram of paste contains 100 milligrams of mebendazole and 454 milligrams of trichlorfon.

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

(c) *Conditions of use*—(1) *Amount*. 8.8 milligrams of mebendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use*. It is used in horses for treatment of infections of bots *(Gastrophilus intestinalis* and *G. nasalis)*, large roundworms *(Parascaris equorum)*, large strongyles *(Strongylus edentatus*, *S. equinus*, *S. vulgaris)*, small strongyles, and pinworms *(Oxyuris equi)*.

(3) *Limitations*. Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not administer simultaneously or within a few days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997]

§ 520.1330 Meclofenamic acid granules.

(a) *Chemical name*. N-(2,6-Dichloromtolyl) anthranilic acid.

(b) *Specifications*. The drug is in granular form containing 5 percent meclofenamic acid.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is used in horses for the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(2) It is administered orally at a dosage of 1 milligram per pound of body weight (1 gram per 1,000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(3) Treatment beyond the initial 5- to 7-day period may be indicated. A maintenance dosage level should be individualized for each animal.

(4) This drug should not be administered to horses with active gastrointestinal, hepatic, or renal disease.

(5) Not for use in horses intended for food.

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

[41 FR 5632, Feb. 9, 1976, as amended at 53 FR 23390, June 22, 1988]

§ 520.1331 Meclofenamic acid tablets.

(a) *Specifications*. Each tablet contains either 10 or 20 milligrams of meclofenamic acid.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 1.1 milligrams per kilogram (0.5 milligram per pound) daily for 5 to 7 days.

(2) *Indications for use*. For the relief of signs and symptoms of chronic inflammatory disease involving the musculoskeletal system.

(3) *Limitations*. For oral use only. Should not be administered to animals with congestive heart failure or active gastrointestinal, hepatic, or renal disease. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 43385, Oct. 25, 1985, as amended at 53 FR 23390, June 22, 1988]

§ 520.1341 Megestrol acetate tablets.

(a) *Specifications*. Each tablet contains 5 or 20 milligrams of megestrol acetate.

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

(c) *Conditions of use*. (1) The drug is used in female dogs for the postponement of estrus and the alleviation of false pregnancy.

(2) It is administered 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.

(3) Full dosage regimen must be completed to produce the desired effect.

(4) Examination of vaginal smears is recommended to confirm detection of proestrus.

(5) Do not administer for more than two consecutive treatments.

(6) Once therapy is started, the animal should be confined for 3 to 8 days or until cessation of bleeding, since dogs in proestrus accept a male.

(7) Do not use prior to or during first estrus cycle.

(8) Do not use in pregnant animals.

(9) Do not use in the presence of a disease of the reproductive system or with mammary tumors.

(10) Should estrus occur within 30 days after cessation of treatment, mating should be prevented.

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

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.1380 Methocarbamol tablets.

(a) *Chemical name.* 3-(O-Methoxyphenoxy)-1,2-propanediol 1-carbamate.

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

(c) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is administered to dogs and cats as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

(2) Dosage is based upon severity of symptoms and response noted. The usual initial dose in 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1390 (S)-methoprene.

(a) *Specifications.* Each capsule contains 154, 308, or 462 milligrams (mg) of (S)-methoprene.

(b) *Sponsor.* See No. 011536 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* Capsules are given orally, once per week at the recommended minimum dosage of 10 mg of (S)-methoprene per pound of body weight (22 mg/kilograms).

(2) *Indications for use.* For oral use in dogs, 9 weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-methoprene prevents and controls flea populations by preventing the development of flea eggs but does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

[65 FR 20730, Apr. 18, 2000]

§ 520.1408 Methylprednisolone tablets.

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

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use of 1- and 4-milligram tablets; see No. 000010 for use of 1- and 2-milligram tablets.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special consideration.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, or cushingoid syndrome. The presence of active tuberculosis, diabetes, osteoporosis, chronic psychotic reactions, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids. Some of these conditions occur only rarely in dogs and cats but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount*. Dogs and cats: 5 to 15 pounds, 2 milligrams; 15 to 40 pounds, 2 to 4 milligrams; 40 to 80 pounds, 4 to 8 milligrams.

(2) *Indications for use*. For use in dogs and cats as an anti-inflammatory agent.

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

[47 FR 52697, Nov. 23, 1982, as amended at 49 FR 20810, May 17, 1984; 50 FR 32844, Aug. 15, 1985; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.1409 Methylprednisolone, aspirin tablets.

(a) *Specifications*. Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use have been NAS/NRC reviewed and found effective. New animal drug applications for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special considerations*. (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with tuberculosis, chronic nephritis, peptic ulcer, or Cushingoid syndrome. The presence of diabetes mellitus, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount*. Dogs under 15 pounds, ¼ to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily.

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

(3) *Limitations*. 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. Do not administer to cats. Do not overdose. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21566, May 13, 1983]

§ 520.1422 Metoserpate hydrochloride.

(a) *Chemical name*. Methyl-*o*-methyl-18-epireserpate hydrochloride.

(b) *Sponsor*. See No. 000003 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.410 of this chapter.

(d) *Conditions of use*. It is used in drinking water for replacement chickens as follows:

(1) *Amount*. 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use*. As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations*. To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount*. 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use*. As an aid in control of hysteria.

(ii) *Limitations*. To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments

at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

§ 520.1430 Mibolerone.

(a) *Specifications*. Each milliliter contains 100 micrograms of mibolerone.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(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.

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

(3) *Limitations*. 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. Mibolerone should not be used in bitches before the first estrous period. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 15625, Apr. 14, 1978]

§ 520.1445 Milbemycin oxime tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats*. Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(b) *Sponsor*. See 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and puppies*—(i) *Amount*. For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).

(ii) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.

(iii) *Limitations*. Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats and kittens*—(i) *Amount*. 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(ii) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations*. Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 25301, June 21, 1990, as amended at 55 FR 49888, Dec. 3, 1990; 58 FR 5608, Jan. 22, 1993; 60 FR 50097, Sept. 28, 1995; 61 FR 43654, Aug. 26, 1996; 63 FR 29352, May 29, 1998; 63 FR 41189, Aug. 3, 1998]

§ 520.1446 Milbemcyin oxime/lufenuron tablets.

(a) *Specifications*. Tablets containing: 2.3 milligrams milbemycin oxime/46 milligrams lufenuron, 5.75 milligrams/115 milligrams, 11.5 milligrams/230 milligrams, and 23 milligrams/460 milligrams.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 milligrams of milbemycin and 10 milligrams of lufenuron per kilogram of body weight.

(ii) *Indications for use*. For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria*

immitis, for prevention and control of flea populations, control of adult *Ancylostoma caninum* (hookworm), and removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations*. Administer tablets once a month, preferably on the same date each time. All dogs in a household should be treated to achieve maximum efficacy. Do not use in dogs less than 4 weeks of age and less than 2 pounds body weight. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998]

§ 520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

[55 FR 3586, Feb. 2, 1990]

§ 520.1448a Monensin blocks.

(a)(1) *Specifications*. Each pound of protein-mineral block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor*. See 036904 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 80 to 200 milligrams of monensin (0.2 to 0.5 pound of block) per head per day.

(ii) *Indications for use*. Increased rate of weight gain.

(iii) *Limitations*. Block to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

(b) [Reserved]

(c)(1) *Specifications*. Each pound of protein block contains 175 milligrams of monensin (0.038 percent) as monensin sodium.

(2) *Sponsor*. See 021676 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day.

(ii) *Indications for use*. Increased rate of weight gain.

(iii) *Limitations*. Blocks to be fed free choice to pasture cattle (slaughter, stocker, and feeder). Provide at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established.

(d)(1) *Specifications*. Each pound of block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor*. See 051267 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day.

(ii) *Indications for use*. Pasture cattle: Increased rate of weight gain.

(iii) *Limitations*. Blocks to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least one block per five head of cattle. Feed blocks continously. Do not feed salt or

mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

[46 FR 19466, Mar. 31, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1448a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.1450 Morantel tartrate oral dosage forms.

§ 520.1450a Morantel tartrate bolus.

(a) *Specifications*. Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount*. One bolus per 500 pounds of body weight (4.4 milligrams per pound of body weight) as a single oral dose. Boluses may be divided in half for more accurate dosing as follows: up to 325 pounds, ½ bolus; 326 to 600 pounds, 1 bolus; 601 to 900 pounds, 1½ boluses; and 901 to 1,200 pounds, 2 boluses.

(2) *Indications for use*. For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(3) *Limitations*. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. Do not treat within 14 days of slaughter.

[46 FR 50949, Oct. 16, 1981. Redesignated at 49 FR 47831, Dec. 7, 1984, and amended at 51 FR 9005, Mar. 17, 1986]

§ 520.1450b Morantel tartrate cartridge.

(a) *Specifications*. The drug product consists of a stainless-steel cylinder having both ends closed with polyethylene diffusing discs and containing a morantel tartrate paste. The paste contains 22.7 grams of morantel tartrate equivalent to 13.5 grams of morantel base.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount*. Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use*. For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum*.

(3) *Limitations*. Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 106 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 47831, Dec. 7, 1984, as amended at 51 FR 23415, June 27, 1986; 51 FR 41081, Nov. 13, 1986]

§ 520.1450c Morantel tartrate sustained-release trilaminate cylinder/sheet.

(a) *Specifications*. The drug product consists of a trilaminated, perforated, plastic sheet formed into a cylinder having plastic plugs in its ends. The core lamina contains 19.8 grams of morantel tartrate equivalent to 11.8 grams of morantel base.

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount*. Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use*. For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum*.

(3) *Limitations*. Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 102 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[56 FR 13396, Apr. 2, 1991]

§ 520.1451 Moxidectin.

(a) *Specifications*. Each tablet contains 30, 68, or 136 micrograms of moxidectin.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.–

(2) *Indications for use*. To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

(3) *Limitations*. Use once-a-month in dogs at 8 weeks of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 37713, July 15, 1997]

§ 520.1452 Moxidectin gel.

(a) *Specifications*. The gel contains 2 percent moxidectin (20 milligrams per milliliter).

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use*. Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated lumenal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)); hairworms (*Trichostrongylus axei* (adults)); large-mouth stomach worms (*Habronema muscae* (adults)); and horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations*. Not for use in horses and ponies intended for food.

[62 FR 42902, Aug. 11, 1997, as amended at 64 FR 66105, Nov. 24, 1999]

§ 520.1468 Naproxen granules.

(a) *Specifications*. Naproxen granules contain 50 percent naproxen.

(b) *Sponsor*. No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*. The drug is used 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 of the horse.

(2)(i) For oral maintenance therapy following initial intravenous dosage, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as top dressing in the animal's feed for up to 14 consecutive days. The

initial intravenous dosage is 5 milligrams per kilogram of body weight.

(ii) For oral dosage only, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as a top dressing in the animal's feed for up to 14 consecutive days.

(3) Not for use in horses intended for food.

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

[41 FR 14188, Apr. 2, 1976, as amended at 51 FR 24525, July 7, 1986; 61 FR 5506, Feb. 13, 1996]

§ 520.1484 Neomycin sulfate soluble powder.

(a) *Specifications*. Neomycin sulfate soluble powder contains 20.3 grams of neomycin sulfate (equivalent to 14.2 grams of neomycin base) per ounce.

(b) *Sponsors*. See 000069, 046573, 051259, and 061133 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See 000009 for use as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances*. See § 556.430 of this chapter.

(d) *Conditions of use*—(1) *Cattle (excluding veal calves), swine, sheep, and goats*.

(i) *Amount*. 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) in divided doses for a maximum of 14 days.

(ii) *Indications for use*. For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

(iii) *Limitations*. Add to drinking water or milk; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

(2) *Turkeys*—(i) *Amount*. 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) for 5 days.

(ii) *Indications for use*. For the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations*. Add to drinking water; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 5 consecutive days.

[64 FR 31497, June 11, 1999, as amended at 66 FR 14073, Mar. 9, 2001]

§ 520.1485 Neomycin sulfate oral solution.

(a) *Specifications*. Each milliliter contains 200 milligrams of neomycin sulfate (equivalent to 140 milligrams of neomycin base).

(b) *Sponsors*. See Nos. 000009, 051259, and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.430 of this chapter.

(d) *Conditions of use*—(1) *Amount*. 10 milligrams of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

(2) *Indications for use*. For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats.

(3) *Limitations*. Administer undiluted or in drinking water. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

[58 FR 38972, July 21, 1993, as amended at 60 FR 3079, Jan. 13, 1995; 61 FR 31398, June 20, 1996; 62 FR 60657, Nov. 12, 1997; 63 FR 45944, Aug. 28, 1998; 65 FR 45877, July 26, 2000; 65 FR 53581, Sept. 5, 2000]

§ 520.1510 Nitenpyram.

(a) *Specifications*. Each tablet contains 11.4 or 57 milligrams of nitenpyram.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs and cats*—(1) *Amount*. One tablet given orally, as needed.

(2) *Indications for use*. For the treatment of flea infestations on dogs, puppies, cats, and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

[65 FR 70662, Nov. 27, 2000]

§ 520.1615 Omeprazole.

(a) *Specifications*. Each gram of oral paste contains 0.37 gram of omeprazole.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. For treatment of gastric ulcers, 1.8 milligrams of omeprazole per pound of body weight (4 milligrams per kilogram) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 milligram of omeprazole per pound of body weight (2 milligrams per kilogram) once daily for at least an additional 4 weeks.

(2) *Indications for use*. For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(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.

[64 FR 18573, Apr. 15, 1999]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications*. Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 2.5 to 7.5 milligrams per kilogram body weight.

(ii) *Indications for use*. For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) *Limitations*. Administer orally once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs and cats during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 29012, May 29, 1997, as amended at 62 FR 61627, Nov. 19, 1997]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications*—(1) *Powder for suspension*. Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets*. Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 10 milligrams per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms *(Parascaris equorum)*, mature and immature pinworms *(Oxyuris equi)*, large strongyles *(Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus)*, and small strongyles.

(3) *Limitations*—(i) *Powder for suspension*. For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets*. The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior to administration is not necessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your

veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[44 FR 35211, June 19, 1979, as amended at 46 FR 26301, May 12, 1981; 46 FR 60570, Dec. 11, 1981; 49 FR 28549, July 13, 1984; 61 FR 5506, Feb. 13, 1996]

§ 520.1629 Oxfendazole paste.

(a)(1) *Specifications*. Each gram of paste contains 0.375 gram oxfendazole (37.5 percent).

(2) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications*. Each gram of paste contains 185 milligrams of oxfendazole (18.5 percent).

(2) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.495 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use*. The drug is used in cattle for the removal and control of the following worms: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata*, *C. oncophora*, and *C. mcmasteri*—adult, L4); and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations*. For use in cattle only. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 11 days after treatment. Do not use in female dairy cattle of breeding age. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 38250, Sept. 28, 1984, as amended at 58 FR 39443, July 23, 1993; 61 FR 5506, Feb. 13, 1996]

§ 520.1630 Oxfendazole suspension.

(a) *Specifications*. Each milliliter contains 90.6 or 225.0 milligrams oxfendazole (9.06 or 22.5 percent).

(b) *Sponsor*. *See* 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. *See* § 556.495 of this chapter.

(d) *Conditions of use*—(1) *Horses* (9.06 percent suspension only).

(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. For removal of large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Administer 9.06 percent suspension by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for food. If administered by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian. If administered by dose syringe only: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Cattle*. (9.06 or 22.5 percent suspension). (i) *Amount*. 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use*. For the removal and control of: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms

(*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata, C. oncophora,* and *C. mcmasteri*—adult, L4), and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations*. For use in cattle only. Administer 9.06 percent suspension orally only with a dose syringe, and 22.5 percent suspension either orally with a dose syringe or intraruminally with a rumen injector. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle. For use of 9.06 percent suspension orally: Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism. For use of 22.5 percent suspension orally or intraruminally: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 46943, Nov. 8, 1990, as amended at 56 FR 8710, Mar. 1, 1991; 61 FR 5506, Feb. 13, 1996]

§ 520.1631 Oxfendazole and trichlorfon paste.

(a) *Specifications*. Each gram of paste contains 28.5 milligrams oxfendazole and 454.5 milligrams trichlorfon.

(b) *Sponsor*. See 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2.5 milligrams of oxfendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of bots (*Gasterophilus intestinalis*, 2nd and 3rd instars; *G. nasalis*, 3rd instar) and the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), pinworms (*Oxyuris equi*), adult and 4th stage larvae; large strongyles (*Strongylus edentatus, S. vulgaris*, and *S. equinus*); and small strongyles.

(3) *Limitations*. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water before use is unnecessary. Administer with caution to sick or debilitated horses. Not for use in horses intended for food. Do not administer to mares during the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not use this product in animals simultaneously with, or within a few days before or after treatment with or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 50291, Dec. 10, 1985, as amended at 61 FR 5506, Feb. 13, 1996]

§ 520.1638 Oxibendazole paste.

(a) *Specifications*. The paste contains 22.7 percent oxibendazole.

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For uses other than for threadworms (*Strongyloides westeri*), 10 milligrams of oxibendazole per kilogram of body weight; for threadworms (*Strongyloides westeri*), 15 milligrams per kilogram.

(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*. Administer orally by syringe. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 50948, Oct. 16, 1981, as amended at 47 FR 36418, Aug. 20, 1982; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1640 Oxibendazole suspension.

(a) *Specifications*. The suspension contains 10 percent oxibendazole.

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For use other than threadworms (*Strongyloides westeri*), 10

milligrams of oxibendazole per kilogram of body weight; for threadworms, 15 milligrams per kilogram of body weight.

(2) *Indications for use.* For removal and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris);* small strongyles (species of the 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.* Administer 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. Prepare individual doses to ensure that each animal receives the correct amount. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 78119, Nov. 28, 1980, as amended at 47 FR 39812, Sept. 10, 1982; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1660 Oxytetracycline.

§ 520.1660a Oxytetracycline and carbomycin in combination.

(a) *Specifications.* (1) Oxytetracycline: The antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(2) Carbomycin: The antibiotic substance produced by growth of *Streptomyces halstedii* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of oxytetracycline in paragraph (e) of this section refer to the activity of oxytetracycline hydrochloride and the quantities of carbomycin listed refer to the activity of an appropriate standard.

(d) *Related tolerances.* See §§ 556.110 and 556.500 of this chapter.

(e) *Conditions of use.* It is used as oxytetracycline hydrochloride plus carbomycin base in drinking water of chickens as follows:

(1) *Amount.* 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon.

(2) *Indications for use.* As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by *Mycoplasma gallisepticum* and secondary bacterial organisms associated with chronic respiratory disease such as *E. coli.*

(3) *Limitations.* Administer for not more than 5 days; not for use in chickens producing eggs for human consumption; withdraw 24 hours before slaughter.

§ 520.1660b Oxytetracycline hydrochloride capsules.

(a) *Specifications.* The drug is in capsule form with each capsule containing 125 or 250 milligrams of oxytetracycline hydrochloride. Oxytetracycline is the antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by *Brucella bronchiseptica,* tonsilitis caused by *Streptococcus hemolyticus,* bacterial enteritis caused by *Escherichia coli,* urinary tract infections caused by *Escherichia coli,* and wound infections caused by *Staphylococcus aureus.*[1]

(2) The drug is administered orally to dogs and cats at a dosage level of 25–50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the severity and degree of involvement and the susceptibility of the infectious

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsidered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.[1]

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications*. Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors*. For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See 000069 for use of 250 and 500 milligram tablets.

(c) *Tolerances*. See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1)(i) *Amount*. 250 milligrams per 100 pounds of body weight every 12 hours (5 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use*. For control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(2)(i) *Amount*. 500 milligrams per 100 pound of body weight every 12 hours (10 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use*. For treatment of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(3) *Limitations*. Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily). For sponsor 000069: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998]

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) *Specifications*. The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 oz.).

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.75 oz; pails: 5 lb).

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

(1) No. 000069 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 046573 for use of OTC HCl concentration in paragraph (a)(4) of this

section in chickens, turkeys, and swine.

(3) No. 000010 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 057561 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, and sheep.

(6) No. 053389 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

(7) No. 061133 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(c) *Related tolerances*. See § 556.500 of this chapter.

(d) *Conditions of use*. (1) It is used in drinking water as follows:

(i) *Chickens*—(A)(*1*) *Amount per gallon*. 200 to 400 milligrams.

(*2*) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(*3*) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(B)(*1*) *Amount per gallon*. 400 to 800 milligrams.

(*2*) *Indications for use*. Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

(*3*) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(ii) *Turkeys*—(A)(*1*) *Amount per gallon*. 200 to 400 milligrams.

(*2*) *Indications for use*. Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

(*3*) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(B)(*1*) *Amount per gallon*. 400 milligrams.

(*2*) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(*3*) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(C)(*1*) *Amount*. 25 milligrams per pound of body weight.

(*2*) *Indications for use*. Growing turkeys. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

(*3*) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to salughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(iii) *Swine*—(A) *Amount*. 10 milligrams per pound of body weight daily.

(B) *Indications for use*. Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia

caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Use as sole source of OTC. Administer up to 14 days; do not use for more than 14 consecutive days; withdraw 5 days prior to slaughter those products sponsored by Nos. 000069 and 059130. Administer up to 5 days; do not use for more than 5 consecutive days; withdraw 13 days prior to slaughter those products sponsored by Nos. 046573 and 057561.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 milligrams per pound of body weight daily.

(B) *Indications for use*. Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

(v) *Sheep*—(A) *Amount*. 10 milligrams per pound of body weight daily.

(B) *Indications for use*. Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Withdraw 5 days prior to slaughter.

(2) It is used in the food of honey bees as follows:

(i) *Amount*. 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture.

(ii) *Indications for use*. Control and treatment of American and European foul brood caused by *Bacillus larvae* susceptible to oxytetracycline.

(iii) *Limitations*. The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow.

[50 FR 32694, Aug. 14, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1660d, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.1696 Penicillin oral dosage forms.

§ 520.1696a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.

(a) *Specifications*. When reconstituted, each milliliter contains penicillin G procaine equivalent to 20,000, 25,000, 40,000, 50,000, 80,000, or 100,000 units of penicillin G.

(b) *Sponsor*. [Reserved]

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*. *Chickens*—It is used in drinking water as follows:

(1) *Amount*. 100,000 units per gallon.

(i) *Indications for use*. Treatment of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) *Limitations*. As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

(2) *Amount*. 50,000 to 100,000 units per gallon.

(i) *Indications for use*. Prevention of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) *Limitations*. As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

[57 FR 37326, Aug. 18, 1992]

§ 520.1696b Penicillin G potassium in drinking water.

(a) *Specifications*. When reconstituted, each milliliter contains penicillin G potassium equivalent to 20,000, 25,000, 40,000, 50,000, 80,000, or 100,000 units of penicillin G.

(b) *Sponsors*. See Nos. 046573, 053501, and 061133 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Turkeys*—(1) *Amount*. 1,500,000 units per gallon drinking water for 5 days.

(2) *Indications for use*. Treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

(3) *Limitations*. Prepare concentrated stock solution for use with medication proportioners fresh every 24 hours. Prepare recommended use levels for gravity flow watering system fresh every 12 hours. For best results, treatment should be started at the first sign of infection. Discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption.

[57 FR 37326, Aug. 18, 1992, as amended at 59 FR 42493, Aug. 18, 1994; 60 FR 26359, May 17, 1995; 62 FR 55160, Oct. 23, 1997; 65 FR 10705, Feb. 29, 2000; 66 FR 14073, Mar. 9, 2001]

§ 520.1696c Penicillin V potassium for oral solution.

(a) *Specifications*. When reconstituted, each milliliter contains 25 milligrams (40,000 units) of penicillin V.

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

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*. *Dogs and cats*—(1) *Amount*. 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use*. Treatment of respiratory, urogenital, skin, and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations*. Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.1696d Penicillin V potassium tablets.

(a) *Specifications*. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

(b) *Sponsors*. See Nos. 017144, 050604, and 053501 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. These conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*. *Dogs and Cats*—(1) *Amount*. 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use*. Treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations*. Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications*. Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

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

(1) No. 000061 for use of 100- or 400-milligram or 1-gram tablets, or 2- or 4-gram boluses, in dogs and horses.

(2) Nos. 000010 and 059130 for use of 100- or 200- milligrams or 1-gram tablets in dogs and horses.

(3) Nos. 000031, 000856, 000864, 058829 and 061133 for use of 100-milligram or 1-gram tablets in dogs and horses.

(4) No. 055246 for use of 100-milligram tablets in dogs.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Twenty milligrams per pound of body weight daily.[1]

(ii) *Indications for use*. The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.[1]

(iii) *Limitations*. Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

(2) *Horses*—(i) *Amount*. One to two grams per 500 pounds weight daily.[1]

(ii) *Indications for use*. This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.[1]

(iii) *Limitations*. Do not exceed a daily dosage of 4 grams per day. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Not for use in animals intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[42 FR 44227, Sept. 2, 1977, as amended at 45 FR 10333, Feb. 15, 1980; 45 FR 14023, Mar. 4, 1980; 46 FR 48642, Oct. 2, 1981; 47 FR 30968, July 16, 1982; 50 FR 49372, Dec. 2, 1985; 52 FR 36023, Sept. 25, 1987; 54 FR 22885, May 30, 1989; 55 FR 8462, Mar. 8, 1990; 59 FR 53585, Oct. 25, 1994; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 63 FR 36178, July 2, 1998; 66 FR 14073, Mar. 9, 2001; 66 FR 14316, Mar. 12, 2001; 66 FR 15349, Mar. 19, 2001]

§ 520.1720b Phenylbutazone granules.

(a) *Specifications*. The drug is in granular form. It is packaged to contain either 8 grams of phenylbutazone per package or 1 gram of phenylbutazone per package.

(b) *Sponsor*. See 000061 in § 510.600(c) for 8-gram package, see 059320 for 1-gram package.

(c) *NAS/NRC status*. The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications*. For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

[1] See footnote 1 to § 520.1660b.

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*. The paste contains 20 percent phenylbutazone.

(b) *Sponsor*. See 000061 and 010797 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

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

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.1720d Phenylbutazone gel.

(a) *Specifications*. Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor*. See 061133 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

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

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001]

§ 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

§ 520.1802a Piperazine-carbon disulfide complex suspension.

(a) *Specifications*. Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Horses and ponies*—(1) *Amount*. One fluid ounce per 100 pounds of body weight.[1]

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum)*, bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongyles* spp.), and pinworms (*Oxyuris equi*).[1]

(3) *Limitations*. Administer by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours. Provide water as usual. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics and other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[45 FR 52781, Aug. 8, 1980]

[1] These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications*. Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses and ponies*—(1) *Amount*. For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.[1]

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).[1]

(3) *Limitations*. Withhold feed overnight or for 8 to 10 hours. Give water just before and/or after treatment. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics or other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.[1]

[45 FR 52782, Aug. 8, 1980]

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

(a) *Specifications*. Each fluid ounce contains 5 grams of piperazine-carbon disulfide complex and 0.83 gram of phenothiazine.

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses and ponies*—(1) *Amount*. One fluid ounce per 100 pounds of body weight.

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, and large strongyles (*Strongylus* spp.).

(3) *Limitations*. See § 520.1802a(c)(3).

[45 FR 52782, Aug. 8, 1980]

§ 520.1803 Piperazine citrate capsules.

(a) *Specifications*. Piperazine citrate capsules contain piperazine citrate equivalent to 140 milligrams of piperazine base in each capsule.

(b) *Sponsor*. See No. 021091 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in dogs and cats for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(2) 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 ½ 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. Reinfection may occur. Repeat treatment if indicated.

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

[40 FR 13838, Mar. 27, 1975, as amended at 54 FR 38515, Sept. 19, 1989]

§ 520.1804 Piperazine phosphate capsules.

(a) *Specifications*. Each capsule contains 120, 300, or 600 milligrams of piperazine phosphate monohydrate.

(b) *Sponsor*. See No. 050906 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 60 milligrams of piperazine phosphate monohydrate per pound of body weight.[1]

(2) *Indications for use*—(i) *Dogs*. It is used for the removal of large roundworms (ascarids) *Toxocara canis* and *Toxascaris leonina*.[1]

(ii) *Cats*. It is used for the removal of large roundworms (ascarids) *Toxocara mystax* and *Toxacaris leonina*.[1]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(3) *Limitations.* Administer in animal's food or milk. For animals up to 1 year of age administer every 2 or 3 months; for animals over 1 year old, administer periodically as necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.[1]

[43 FR 6941, Feb. 17, 1978; 43 FR 9804, Mar. 10, 1978, as amended at 46 FR 20158, Apr. 3, 1981]

§ 520.1805 Piperazine phosphate with thenium closylate tablets.

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate) or 500 milligrams piperazine hexahydrate (as piperazine phosphate) and 250 milligrams thenium (as thenium closylate).

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

(c) *Conditions of use*—(1) *Amount.* Administer orally to dogs as follows:

NUMBER OF TABLETS AT EACH OF THE TWO DOSES

Animal weight (lb)	375 mg	750 mg
2 but less than 5	½	.....
5 but less than 10	1	½
10 or heavier	2	1

(2) *Indications for use.* For removal of immature (fourth stage larvae) and adult hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) and ascarids (*Toxocara canis*) from weaned pups and adult dogs.

(3) *Limitations.* Do not use this product to treat dogs weighing less than 2 pounds, unweaned pups, or pups under 5 weeks of age. Maximum efficacy against hookworms necessitates two doses in 1 day of treatment. The interval between the doses should be not less than 4 hours or more than 24 hours. Administer the first dose in the morning before feeding. Do not permit dog to chew tablet. Feed the dog between doses. Do not feed milk or other fatty foods during treatment. Retreatment may be needed in 7 to 28 days as determined by laboratory fecal examinations or in animals kept in known contaminated quarters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 32747, July 28, 1978, as amended at 47 FR 55476, Dec. 10, 1982; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.1806 Piperazine monohydrochloride liquid.

(a) *Specifications.* The product contains 4.77 percent piperazine monohydrochloride, equivalent to 3.35 percent piperazine base.

(b) *Sponsor.* See Nos. 017135 and 063765 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For dogs for the removal of roundworms (*Toxocara canis* and *Toxascaris leonina*).

(2) *Dosage.* Administer 20 to 30 milligrams of piperazine base per pound of body weight as a single dose.

(3) *Limitations.* Administer by mixing into the animal's ration to be consumed at one feeding. For animals in heavily contaminated areas, reworm at monthly intervals. Not for use in unweaned pups or animals less than three weeks of age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[47 FR 20758, May 14, 1982, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 59 FR 28769, June 3, 1994; 63 FR 8348, Feb. 19, 1998]

§ 520.1807 Piperazine.

(a) *Specifications.* A soluble powder or liquid containing piperazine dihydrochloride or dipiperazine sulfate, equivalent to 17, 34, or 230 grams of piperazine per pound or 100 milliliters.

(b) *Sponsor.* See 015565 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.513 of this chapter.

(d) *Conditions of use*— (1) *Chickens*—(i) *Amount.* 50 milligrams per bird under 6 weeks, 100 milligrams per bird over 6 weeks.

(ii) *Indications for use.* For removal of large roundworm (*Ascaridia* spp.).

(iii) *Limitations.* For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 14 days prior to slaughter. Do not use for chickens producing eggs for human consumption. Consult your

veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Turkeys*—(i) *Amount*. 100 milligrams per bird up to 12 weeks and 200 milligrams per bird over 12 weeks.

(ii) *Indications for use*. For removal of large roundworm (*Ascaridia* spp.).

(iii) *Limitations*. For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 14 days prior to slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Swine*—(i) *Amount*. 50 milligrams per pound of body weight.

(ii) *Indications for use*. For removal of large roundworm (*Ascaris suum*) and nodular worms (*Oesophagostomum* spp.).

(iii) *Limitations*. For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 21 days prior to slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[64 FR 23018, Apr. 29, 1999]

§ 520.1840 Poloxalene.

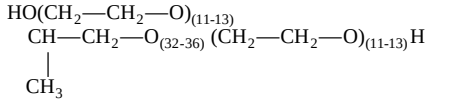
(a) *Chemical name*. Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.

(b) *Specifications*. (1) Molecular weight range: 2,850 to 3,150.

(2) Hydroxyl number: 35.7 to 39.4.

(3) Cloud point (10 percent solution): 42° C.–46° C.

(4) Structural formula:



(c) *Sponsor*. (1) See No. 000069 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(1) of this section.

(2) See No. 000069 in § 510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(3) of this section.

(3) See No. 036904 in § 510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(2) of this section.

(4) See No. 017800 in § 510.600(c) of this chapter for sponsor of the usage provided by paragraph (d)(4) of this section.

(d) *Conditions of use*. (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 oz. of block (1.5 grams poloxalene) per 100 lbs. of body weight per day.

(3) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle. A 53-percent poloxalene top dressing on individual rations of ground feed. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat use of the drug if animals are exposed to bloat-producing conditions for more than 12 hours after the last treatment. Do not exceed the double dose in any 24-hour period.

(4) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle. Administer in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 ounce of block (1.5 grams of poloxalene) per 100 pounds of body weight per day. Provide access to blocks at least 7 days before exposure to bloat-producing conditions.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39857, Aug. 29, 1975; 42 FR 41854, Aug. 19, 1977; 50 FR 5385, Feb. 8, 1985; 54 FR 33501, Aug. 15, 1989; 56 FR 50653, Oct. 8, 1991; 58 FR 26523, May 4, 1993; 60 FR 55659, Nov. 2, 1995]

§ 520.1846 Polyoxyethylene (23) lauryl ether blocks.

(a) *Specifications*. Each molasses-based block contains 2.2 percent polyoxyethylene (23) lauryl ether.

(b) *Sponsor*. See No. 050112 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 grams of polyoxyethylene (23) lauryl ether per 100 kilograms of body weight per day (1 pound of block per 500 kilogram (1,100 pound) animal per day).

(2) *Indications for use*. For reduction of the incidence of bloat (alfalfa and clover) in pastured cattle.

(3) *Limitations*. Administer free-choice to beef cattle and nonlactating dairy cattle only. Initially, provide one block per five head of cattle. Start treatment 10 to 14 days before exposure to bloat-producing pastures. Do not allow cattle access to other sources of salt while being fed this product. Do not feed this product to animals without adequate forage/roughage consumption.

[50 FR 48189, Nov. 22, 1985, as amended at 56 FR 9841, Mar. 8, 1991]

§ 520.1870 Praziquantel tablets.

(a) *Specifications*. Each dog tablet contains 34 milligrams (mg) of praziquantel; each cat tablet contains 11.5 or 23 mg of praziquantel.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use*. For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*. If labeled for use by or on the order of a licensed veterinarian, for removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(ii) *Dosage*. Dogs 5 pounds and under, ½ tablet (17 mg); 6 to 10 pounds, 1 tablet (34 mg); 11 to 15 pounds, 1½ tablets (51 mg); 16 to 30 pounds, 2 tablets (68 mg); 31 to 45 pounds, 3 tablets (102 mg); 46 to 60 pounds, 4 tablets (136 mg); over 60 pounds, 5 tablets maximum (170 mg).

(iii) *Limitations*. Administer directly by mouth or crumbled and in feed. Not intended for use in puppies less than 4 weeks of age. For over-the-counter (OTC) use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism. For prescription use: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Indications for use*. For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(ii) *Dosage*. Cats 4 pounds and under, 11.5 mg; 5 to 11 pounds, 23 mg; over 11 pounds, 34.5 mg.

(iii) *Limitations*. Administer directly by mouth or crumbled and in feed. Not intended for use in kittens less than 6 weeks of age. For OTC use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 60570, Dec. 11, 1981, as amended at 47 FR 26377, June 18, 1982; 55 FR 2234, Jan. 23, 1990; 58 FR 7864, Feb. 10, 1993; 58 FR 42853, Aug. 12, 1993]

§ 520.1871 Praziquantel/pyrantel pamoate tablets.

(a) *Specifications*. Each cat tablet contains 18.2 milligrams (mg) praziquantel with 72.6 mg pyrantel (as pyrantel pamoate).

(b) *Sponsor*. See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Cats*—(i) *Dosage*. 1.5 to 1.9 pounds, 1/4 tablet; 2 to 3 pounds, 1/2 tablet; 4 to 8 pounds, 1 tablet; 9 to 12 pounds, 1 1/2 tablets; 13 to 16 pounds, 2 tablets.

(ii) *Indications for use*. For removal of tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*), hookworms (*Ancylostoma tubaeforme*), and large roundworms (*Toxocara cati*) in cats and kittens.

(iii) *Limitations*. Not for use in kittens less than 1 month of age or weighing less than 1.5 pounds. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated. Consult your veterinarian before giving to sick or pregnant animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) [Reserved]

[58 FR 58652, Nov. 3, 1993]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

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

(1) Tablet No. 1: 22.7 milligrams praziquantel, 22.7 milligrams pyrantel base, and 113.4 milligrams febantel; or

(2) Tablet No. 2: 68 milligrams praziquantel, 68 milligrams pyrantel base, and 340.2 milligrams febantel.

(b) *Sponsor*. See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer as a single dose directly by mouth or in a small amount of food as follows:

Weight of animal		Number of tablets per dose	
Kilograms	Pounds	Tablet no. 1	Tablet no. 2
0.9 to 1.8	2 to 4	1/2	
2.3 to 3.2	5 to 7	1	
3.6 to 5.4	8 to 12	1 1/2	
5.9 to 8.2	13 to 18	2	
8.6 to 11.4	19 to 25	2 1/2	
11.8 to 13.6	26 to 30		1
14.1 to 20.0	31 to 44		1 1/2
20.4 to 27.2	45 to 60		2
27.7 to 33.6	61 to 74		2 1/2
34.0 to 40.9	75 to 90		3
41.3 to 47.2	91 to 104		3 1/2
47.7 to 54.5	105 to 120		4

(ii) *Indications for use*. For the removal of tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*); hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*); ascarids (*Toxocara canis*, *Toxascaris leonina*); and whipworms (*Trichuris vulpis*) and for the removal and control of tapeworm *Echinococcus multilocularis* in dogs.

(iii) *Limitations*. Do not use in pregnant animals. Do not use in dogs weighing less than 0.9 kilogram (2 pounds) or puppies less than 3 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 33908, July 1, 1994, as amended at 61 FR 29651, June 12, 1996]

§ 520.1880 Prednisolone tablets.

(a) *Specifications*. Each tablet contains 5 or 20 milligrams prednisolone.

(b) *Sponsor*. See No. 061690 in § 510.600(c)(2) of this chapter.

(c) *Special considerations*. (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Do not use in viral infections. Systemic therapy with prednisolone is contraindicated in animals with peptic ulcer, corneal ulcer, and Cushingoid syndrome. The presence of diabetes, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, renal insufficiency, and active tuberculosis necessitates carefully controlled use. Some of the above conditions occur only rarely in dogs but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(d) *Conditions of use*—(1) *Amount*. Dogs: 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 in dogs as an anti-inflammatory agent.

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

[57 FR 4718, Feb. 7, 1992, as amended at 60 FR 57832, Nov. 22, 1995; 63 FR 148, Jan. 5, 1998]

§ 520.1900 Primidone tablets.

(a) *Specifications*. Each tablet contains 50 or 250 milligrams of primidone.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for use of 250 milligram tablets; see No. 000856 in § 510.600(c) of this chapter for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs*—(1) *Amount*. Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.[1]

(2) *Indications for use*. For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.[1]

(3) *Limitations*. The tablets may be administered whole or crushed and mixed with the food. When convulsions are frequent, the dosage should be divided and administered at intervals. Reduction in dosage should be made gradually and never be abruptly discontinued. Do not use in feline species,

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

as primidone appears to have a specific neurotoxicity in cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[42 FR 61594, Dec. 6, 1977, as amended at 43 FR 55386, Nov 28, 1978; 46 FR 8467, Jan. 27, 1981; 46 FR 57477, Nov. 24, 1981; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35076, June 30, 1997]

§ 520.1920 Prochlorperazine, isopropamide sustained release capsules.

(a) *Specifications*. Prochlorperazine, isopropamide sustained release capsules contain 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. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the treatment of dogs in which gastrointestinal disturbances are associated with emotional stress.

(2)(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.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1921 Prochlorperazine, isopropamide, with neomycin sustained-release capsules.

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

(1) Capsule No. 1: 3.33 milligrams of prochlorperazine (as the dimaleate), 1.67 milligrams of isopropamide (as the iodide), and 25 milligrams of neomycin base (as the sulfate); or

(2) Capsule No. 3: 10 milligrams of prochlorperazine (as the dimaleate), 5 milligrams of isopropamide (as the iodide), and 75 milligrams of neomycin base (as the sulfate).

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer capsules orally twice daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 3
10 to 20	1	
20 to 30	2	
Over 30	3	1
Over 60		2

(2) *Indications for use*. For treatment of dogs in which infectious bacterial gastroenteritis is associated with emotional stress.

(3) *Limitations*. Do not continue medication longer than 5 days. Overdosage or prolonged administration may produce nephrotoxicity as manifested by albuminuria, presence of granular casts and depressed urinary output. If it is desirable to administer a vasoconstrictor, norepinephrine is the drug of choice. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1962 Promazine hydrochloride.

(a)(1) *Chemical name*. 10-[3-(Dimethylamino)propyl]phenothiazine monohydrochloride.

(2) *Specifications*. Conforms to N.F. XII.

(3) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(4) [Reserved]

(5) *Conditions of use*. (i) The drug is used for quieting excitable, unruly, or intractable horses. It is administered at a dosage level of 0.45 to 0.9 milligrams of promazine hydrochloride per pound of body weight mixed with an amount of feed that will be readily consumed.

(ii) Do not use in horses intended for food.

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

(b) [Reserved]

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 55386, Nov. 28, 1978; 59 FR 5705, Feb. 8, 1994]

§ 520.2002 Propiopromazine hydrochloride.

(a) *Chemical name*. 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications*. The drug is administered in a chewable tablet containing 10 to 20 milligrams of propiopromazine hydrochloride.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is intended for oral administration to dogs as a tranquilizer. It is used 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.

(2) It is administered at the rate of 0.5 to 2 milligrams of propiopromazine hydrochloride per pound of body weight once or twice daily depending upon the degree of tranquilization desired.

NOTE: Not for use with organophosphates and/or procaine hydrochloride, as phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Overdosage may produce significant depression.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996]

§ 520.2041 Pyrantel pamoate chewable tablets.

(a) *Specifications*. Each tablet contains pyrantel pamoate equivalent to 22.7 or 113.5 milligrams pyrantel base.

(b) *Sponsor*. See Nos. 017135 and 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Provides at least 2.27 milligrams pyrantel base per pound body weight for dogs weighing more than 5 pounds, and at least 4.54 milligrams of pyrantel base per pound body weight for dogs weighing 5 pounds or less.

(2) *Indications for use*—(i) *In dogs and puppies*. For removal of ascarids (*Toxocara canis; Toxascaris leonina*) and hookworms (*Ancylostoma caninum; Uncinaria stenocephala*).

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis*.

(3) *Limitations*. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications*. Each tablet contains pyrantel pamoate equivalent to 22.7, 45.4, or 113.5 milligrams of pyrantel base.

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is used for dogs as follows:

(1) *Amount*. For dogs weighing over 5 pounds, use at least 2.27 milligrams of pyrantel base per pound of body weight; for dogs weighing 5 pounds or less, use at least 4.54 milligrams of pyrantel base per pound of body weight.

(2) *Indications for use*. For removal and control of large roundworms (ascarids) *(Toxocara canis* and *Toxascaris leonina)*, and hookworms *(Ancylostoma caninum* and *Uncinaria stenocephala)*.

(3) *Limitations*. Administer orally directly or in a small amount of food. To prevent reinfection of *T. canis* in puppies, lactating bitches after whelping, and adult dogs; treat puppies 2, 3, 4, 6, 8, and 10 weeks of age; treat lactating bitches 2 to 3 weeks after whelping; routinely treat adult dogs monthly. Do not withhold food prior to or after treatment. The presence of these parasites should be confirmed by laboratory fecal examination. A followup fecal examination should be conducted

2 to 4 weeks after first treatment regimen to determine the need for re-treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 52700, Nov. 14, 1978, as amended at 49 FR 22073, May 25, 1984; 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993]

§ 520.2043 Pyrantel pamoate suspension.

(a)(1) *Specifications.* Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 50 milligrams of pyrantel base per milliliter.

(2) *Sponsors.* See Nos. 000069 and 059130 in § 510.600(c) of this chapter.

(3) *Conditions of use.* It is used in horses and ponies as follows:

(i) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

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

(iii) *Limitations.* Administered as a single dose mixed with the usual grain ration, or by stomach tube, or by dose syringe. Not for use in horses and ponies to be slaughtered for food purposes. When the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.'' When the drug is not for administration by stomach tube, it shall be labeled: ''Consult your veterinarian for assistance in the diagnosis, control, and treatment of parasitism.''

(b)(1) *Specifications.* Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 2.27 or 4.54 milligrams of pyrantel base per milliliter.

(2) *Sponsors.* See Nos. 000069, 011615, and 059130 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 023851 for use of 4.54 milligrams per milliliter product.

(3) *Conditions of use.* It is used in puppies and dogs as follows:

(i) *Amount.* Equivalent of 2.27 milligrams of pyrantel base per pound of body weight.

(ii) *Indications for use.* For the removal of large roundworms *(Toxocara canis* and *Toxascarias leonina)* and hookworms *(Ancylostoma caninum* and *Uncinaria stenocephala).*

(iii) *Limitations.* Administer in the animal's feed bowl as a single dose by itself or mixed in a small quantity of food. Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(4) *Conditions of use.* It is used in puppies and adult dogs and in lactating bitches after whelping as follows:

(i) *Amount.* Equivalent to 2.27 milligrams of pyrantel base per pound of body weight.

(ii) *Indications for use.* To prevent reinfections of *Toxocara canis.*

(iii) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

[42 FR 28534, June 3, 1977, as amended at 44 FR 36381, June 22 1979; 45 FR 10760, Feb. 19, 1980; 47 FR 16776, Apr. 20, 1982; 51 FR 11440, Apr. 3, 1986; 61 FR 29477, June 11, 1996; 61 FR 63712, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 63 FR 39727, July 24, 1998; 63 FR 45945, Aug. 28, 1998]

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications.* Each milliliter of paste contains 180 milligrams of pyrantel base (as pyrantel pamoate).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses and ponies as follows:

(1) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

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

(3) *Limitations.* Administer as single dose by depositing paste on dorsum of

the tongue using the dose syringe. Not for use in horses intended for food. It is recommended that severely debilitated animals not be treated with this preparation. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[47 FR 47377, Oct. 26, 1982; 48 FR 3367, Jan. 25, 1983]

§ 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

(a) *Specifications*. (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.

(2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.

(b) *Sponsor*. (1) See No. 000069 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (d) (1) and (2) of this section.

(2) See No. 060594 in § 510.600(c) of this chapter, for conditions of use provided for in paragraph (d)(3) of this section.

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

(d) *Conditions of use*. It is used in: (1) Horses and ponies:

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

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

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

(ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug.

(iv) Warning: Do not use in horses or colts intended for food.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 28769, June 3, 1994]

§ 520.2087 Roxarsone soluble powder.

(a) *Specifications*. Each ounce (avoirdupois) of soluble powder contains 21.7 grams of roxarsone (monosodium 3-nitro-4-hydroxyphenylarsonate).

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.60 of this chapter.

(d) *NAS/NRC status*. These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(e) *Conditions of use*—(1) *Growing chickens and growing turkeys*—(i) *Amount*. 0.002 percent roxarsone in drinking water (one packet per each 250 gallons of drinking water).

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

(iii) *Limitations.* Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(2) *Swine*—(i) *Amount.* 0.01 percent roxarsone in drinking water (one packet per each 50 gallons of drinking water); or 30 milliliters of a 1.55 percent roxarsone solution (one packet per 3 pints of water) per 50 pounds of body weight as a drench.

(ii) *Indications for use.* As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).

(iii) *Limitations.* Administer drinking water continuously for not more than 6 days. Administer drench once daily for 1 or 2 days. If no improvement is observed, consult a veterinarian. Treatment may be repeated after 5 days. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

[46 FR 41039, Aug. 14, 1981, as amended at 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992]

§ 520.2088 Roxarsone tablets.

(a)(1) *Specifications.* Each tablet contains 36 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.60 of this chapter.

(4) *NAS/NRC status.* The weight gain, feed efficiency, and pigmentation claims are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(5) *Conditions of use*—(i) *Growing chickens and growing turkeys—(a) Amount.* Dissolve 2 tablets in each gallon of drinking water (0.002 percent roxarsone).

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

(*c*) *Limitations.* Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) *Growing chickens*—(*a*) *Amount.* Dissolve 8 tablets in each gallon of drinking water (0.008 percent roxarsone).

(*b*) *Indications for use.* As an aid in the prevention of coccidiosis due to *Eimeria tenella*.

(*c*) *Limitations.* Administer for not more than 10 consecutive days. Treatment may be repeated after 5 days off medication. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(b)(1) *Specifications.* Each tablet contains 400 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.60 of this chapter.

(4) *NAS/NRC status.* These conditions are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(5) *Conditions of use*—(i) *Swine*—(*a*) *Amount.* 1 tablet (400 milligrams) per gallon of drinking water for no more than 6 days, or 1 tablet (400 milligrams) per 2 fluid ounces of warm water per 50 pounds of body weight as a drench once daily for 1 to 2 days.

(*b*) *Indications for use.* As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).

(*c*) *Limitations.* Treatment may be repeated after 5 days off medication. If no improvement is observed, consult a veterinarian. Treated animals must consume enough medicated water to provide a therapeutic dose. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) [Reserved]

(c)(1) *Specifications.* Each tablet contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.60 of this chapter.

(4) *Conditions of use in growing chickens and growing turkeys*—(i) *Amount.* 1 tablet in each gallon of drinking water (0.002 percent roxarsone).

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

(iii) *Limitations*. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[46 FR 41040, Aug. 14, 1981, as amended at 46 FR 42448, Aug. 21, 1981; 47 FR 15238, Apr. 9, 1982; 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992; 58 FR 65664, Dec. 16, 1993; 65 FR 10705, Feb. 29, 2000]

§ 520.2089 Roxarsone liquid.

(a) *Specifications*. Each teaspoon (5 milliliters) of solution contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.60 of this chapter.

(d) *Conditions of use in growing chickens and growing turkeys*—(1) *Amount*. 1 teaspoon (5 milliliters) to each gallon of drinking water (0.002 percent roxarsone).

(2) *Indications for use*. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) *Limitations*. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[58 FR 65665, Dec. 16, 1993, as amended at 65 FR 10705, Feb. 29, 2000]

§ 520.2095 Sarafloxacin soluble powder.

(a) *Specifications*. Each 145 grams (5.1 ounces) pouch contains sarafloxacin hydrochloride equivalent to 14.5 grams of sarafloxacin base.

(b) *Sponsor*. See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.594 of this chapter.

(d) *Conditions of use*. Used in drinking water as follows:

(1) *Amount*. Chickens—20 to 40 parts per million for 5 consecutive days as the only source of drinking water. Turkeys—30 to 50 parts per million for 5 consecutive days as the only source of drinking water.

(2) *Indications for use*. For control of mortality in growing turkeys and broiler chickens associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations*. No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with a dose in excess of that recommended may result in drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. The effects of sarafloxacin on the reproductive function of treated fowl have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 50097, Sept. 28, 1995]

§ 520.2098 Selegiline hydrochloride tablets.

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

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs*—(1) *Dosage*. 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(i) *Indications for use*. For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) *Limitations*. Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dosage*. 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use*. For the control of clinical signs associated with canine cognitive dysfunction syndrome.

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

[62 FR 34632, June 27, 1997; 62 FR 55159, Oct. 23, 1997, as amended at 63 FR 29551, June 1, 1998; 64 FR 2122, Jan. 13, 1999]

§ 520.2100 Selenium, vitamin E capsules.

(a) *Specifications.* The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium) and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate.)

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

(c) *Conditions of use.* (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

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

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

§ 520.2122 Spectinomycin dihydrochloride oral solution.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. The drug is packaged as an aqueous solution containing 50 milligrams of spectinomycin activity per milliliter.

(b) *Sponsors.* (1) See No. 059130 in § 510.600(c) of this chapter.

(2) See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(2) It is administered orally at the rate of 50 milligrams per 10 pounds body weight twice daily for 3 to 5 days.

(3) Do not administer to pigs over 15 pounds body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996; 65 FR 45877, July 26, 2000]

§ 520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.

§ 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs in the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(2) The drug is administered orally to provide 10 milligrams per pound of body weight twice daily. The tablets may be placed in the animal's mouth or crushed and administered in milk or in the feed. Dosage may be continued

for 4 consecutive days. Should no improvement be observed, discontinue drug and redetermine diagnosis.

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

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001]

§ 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.

(a) *Specifications*. The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor*. See No. 061133 in § 510.600(c) of this chapter.

(c) *Special considerations*. The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Related tolerances*. See § 556.600 of this chapter.

(e) *Conditions of use*. (1) It is administered in the drinking water of growing chickens at 2 grams of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination It is administered as an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO). Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(2) It is administered in the drinking water of floor-raised broiler chickens at 0.5 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination. It is administered for increased rate of weight gain and improved feed efficiency. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(3) It is administered in drinking water of broiler chickens at 1 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 to 5 days of life as an aid in controlling infectious synovitis due to *Mycoplasma synoviae*. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001]

§ 520.2150 Stanozolol oral dosage forms.

§ 520.2150a Stanozolol tablets.

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

(b) *Sponsor*. No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Used as an anabolic steroid treatment in dogs and cats.

(2) Administered orally to cats and small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

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

[40 FR 46101, Oct. 6, 1975, as amended at 42 FR 36995, July 19, 1977. Redesignated at 50 FR 38114, Sept. 20, 1985, and amended at 55 FR 23076, June 6, 1990]

§ 520.2150b Stanozolol chewable tablets.

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

(b) *Sponsor*. No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Used as an anabolic steroid treatment in dogs.

(2) Administered orally to small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks.

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

[50 FR 38114, Sept. 20, 1985, as amended at 55 FR 23076, June 6, 1990]

§ 520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.

§ 520.2158a Streptomycin sulfate oral solution.

(a) *Specifications*. Solution containing 25 percent streptomycin sulfate.

(b) *Sponsor*. See Nos. 033008 and 055462 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.610 of this chapter.

(d) *Conditions of use*. Use in drinking water as follows:

(1) *Calves and swine*—(i) *Amount*. 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon).

(ii) *Indications for use*. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

(iii) *Limitations*. Calves: Do not administer for more than 5 days. Swine: Do not administer for more than 4 days. Prepare fresh solution daily. Calves: Withdraw 2 days before slaughter. As sole source of streptomycin. Warning: Certain strains of bacteria may develop a tolerance for streptomycin. Consult a veterinarian or animal pathologist for diagnosis.

(2) *Chickens*—(i) *Amount*. 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon).

(ii) *Indications for use*. Treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.

(iii) *Limitations*. Chickens: Do not administer for more than 5 days. Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Prepare fresh solution daily. As sole source of streptomycin. Warning: Certain strains of bacteria may develop a tolerance for streptomycin. Consult a veterinarian or animal pathologist for diagnosis.

[57 FR 37327, Aug. 18, 1992, as amended at 58 FR 47211, Sept. 8, 1993; 63 FR 51821, Sept. 29, 1998]

§ 520.2158b Dihydrostreptomycin tablets.

(a) *Specifications*. Each tablet contains 37.5 milligrams dihydrostreptomycin (as the sulfate) with 375 milligrams chlorhexidine dihydrochloride.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.120 and 556.200 of this chapter.

(d) *Conditions of use*. *Calves*—(1) *Amount*. 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.

(2) *Indications for use*. Treatment of bacterial scours in calves.

(3) *Limitations*. Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[57 FR 37327, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.2158c Dihydrostreptomycin oral suspension.

(a) *Specifications*. Each milliliter contains 1.25 milligrams dihydrostreptomycin (as the sulfate) with 12.5 milligrams chlorhexidine dihydrochloride.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.120 and 556.200 of this chapter.

(d) *Conditions of use*. *Calves*—(1) *Amount*. 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.

(2) *Indications for use*. Treatment of bacterial scours in calves.

(3) *Limitations*. Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[57 FR 37327, Aug. 18, 1992]

§ 520.2160 Styrylpyridinium, diethylcarbamazine oral dosage forms.

§ 520.2170 Sulfabromomethazine sodium boluses.

(a) *Specifications*. Each bolus contains 15 grams of sulfabromomethazine sodium.

(b) *Related tolerance*. See § 556.620 of this chapter.

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

(d) *NAS/NRC status*. These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(e) *Conditions of use*. *Cattle*—(1) *Amount*. 90 milligrams per pound body weight.

(2) *Indications for use*. Treatment of necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum;* colibacillosis (scours)

caused by *Escherichia coli;* bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; acute metritis and acute mastitis caused by *Streptococcus* spp.

(3) *Limitations.* Administer orally; repeat in 48 hours if necessary; 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; discontinue use if hematuria, crystalluria or severe depression are noticed; if signs persist after 2 or 3 days consult a veterinarian.

[47 FR 30243, July 13, 1982, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.2184 Sodium sulfachloropyrazine monohydrate.

(a) *Chemical name.* 2-Sulfamido-6-chloroxyrazine, sodium.

(b) *Sponsor.* See Nos. 010042 in § 510.600(c) of this chapter.

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

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

(1) *Amount.* 0.03 percent.

(2) *Indications for use.* Treatment of coccidiosis.

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

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985; 54 FR 12188, Mar. 24, 1989; 55 FR 8460, Mar. 8, 1990; 64 FR 15684, Apr. 1, 1999]

§ 520.2200 Sulfachlorpyridazine oral dosage forms.

§ 520.2200a Sulfachlorpyridazine bolus.

(a) *Chemical name. N′*-6-(Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range: 190° C to 191° C.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

(e) *Conditions of use.* It is used in calves as follows:

(1) *Amount.* 30 to 45 milligrams per pound body weight per day.

(2) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(3) *Limitations.* Administer in a bolus containing 2 grams of sulfachlorpyridazine for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 7 days after the last treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2200b Sulfachlorpyridazine medicated milk and drinking water.

(a) *Chemical name.* N′-(6-Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range: 190 °C to 191 °C.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

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

(1) *Calves*—(i) *Amount.* 30 to 45 milligrams per pound body weight per day.

(ii) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine in milk or milk-replacer formulations for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 7 days after the last treatment.

(2) *Swine*—(i) *Amount.* 20 to 35 milligrams per pound body weight per day.

(*a*) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(*b*) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine in drinking water for 1 to 5 days; for individual treatment, administer orally in divided doses twice daily; treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

(ii) *Amount.* 20 to 35 milligrams per pound body weight per day.

(*a*) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(*b*) *Limitations*. Administer individually in an oral suspension containing 50 milligrams of sulfachlorpyridazine per milliliter in divided doses twice daily for 1 to 5 days; treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2200c Sulfachlorpyridazine tablets.

(a) *Specifications*. Sulfachlorpyridazine tablets contain 250 milligrams of sulfachlorpyridazine per tablet.

(b) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs as a broad spectrum antibacterial agent to aid in the treatment of infectious tracheobronchitis and infections caused by *E. coli*. It can also be used in the treatment of infections caused by other gram-positive and gram-negative organisms that are susceptible to sulfonamide therapy.

(2) It is administered orally at a dosage level of 500 milligrams per 10 to 15 pounds of body weight daily, in two or three divided doses.

(3) The administration of the drug should be discontinued if a response is not noted within 7 to 10 days.

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

[43 FR 36622, Aug. 18, 1978, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) *Approvals*. (1) For oral solution containing 12.5 percent (3.75 grams per ounce) sulfadimethoxine, see Nos. 000010, 000069, 051259, 057561, and 059130 in § 510.600(c).

(2) For soluble powder, each package containing the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt), see Nos. 000069, 051259, 057561, and 059130 in § 510.600(c).

(b) *Special considerations*. Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders.

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

(d) *Conditions of use*. The oral solution is administered as a cattle drench or diluted as directed to prepare drinking water. The powder is used to prepare a drench or drinking water. The concentrations and uses of the various solutions are as follows:

(1) *Broiler and replacement chickens only*. (i) *Amount*. 1.875 (0.05 percent) grams per gallon.

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

(iii) *Limitations*. Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(2) *Meat-producing turkeys only*—(i) *Amount*. 0.938 (0.025 percent) grams per gallon.

(ii) *Indications for use*. Treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations*. Administer for 6 consecutive days; do not administer to turkeys over 24 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(3) *Dairy calves, dairy heifers, and beef cattle only*—(i) *Amount*. 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.

(ii) *Indications for use*. Treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

(iii) 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; in drinking water or drench; available as a sulfadimethoxine soluble powder or a 12.5 percent sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat

beyond 5 days; withdraw 7 days before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 58 FR 6092, Jan. 26, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 8371, Feb. 25, 1997; 62 FR 23357, Apr. 30, 1997; 62 FR 35076, June 30, 1997; 62 FR 40932, July 31, 1997; 63 FR 59714, Nov. 5, 1998; 64 FR 18572, Apr. 15, 1999]

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Sponsors*. Approval to firms identified in § 510.600(c) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(2) To 000061, approval for use as in paragraph (d)(2).

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

(c) [Reserved]

(d) It is used as follows:

(1) *Cattle*—(i) *Amount*. 1.25 to 2.5 grams per 100 pounds body weight.

(ii) *Indications for use*. Treatment of foot rot, bacterial pneumonia, shipping fever, and calf diphtheria.

(iii) *Limitations*. 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 from 4 to 5 days; 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.

(2) *Dogs and cats*. (i) *Amount*. 12.5 to 25 milligrams per pound of body weight.

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

(iii) *Limitations*. Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Beef cattle and nonlactating dairy cattle*—(i) *Amount*. 12.5-gram-sustained-release bolus.

(ii) *Indications for use*. Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella spp*. sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

(iii) *Limitations*. Administer one 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. Do not use in lactating dairy cattle. Do not administer within 12 days of slaughter. During treatment make certain that animals maintain adequate water intake. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999]

§ 520.2220c Sulfadimethoxine oral suspension.

(a) *Chemical name*. *N′*-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Specifications*. Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) *Sponsor*. See Nos. 000061 and 000069 in § 510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2220d Sulfadimethoxine-ormetoprim tablets.

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

1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

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

(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 *Escherichia coli*, *Staphlococcus* spp., and *Proteus mirabilus* susceptible to ormetoprim-potentiated sulfadimethoxine.

(3) *Limitations*. Continue treatment until patient is asymptomatic for 48 hours, but do not exceed a total of 21 consecutive days. Maintain adequate water intake during the treatment period. Safety in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 48593, Nov. 24, 1989, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 61 FR 46719, Sept. 5, 1996]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) *Chemical name*. *N′*-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications*. Melting point range of 180° C. to 186° C.

(c) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

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

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

(1) *Swine*—(i) *Amount*. 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).

(ii) *Indications for use*. Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella cholerasuis* infection.

(iii) *Limitations*. 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 as sodium sulfaethoxypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount*. 2.5 grams per gallon (0.066 percent).

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

(iii) *Limitations*. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

§ 520.2240b Sulfaethoxypyridazine tablets.

(a) *Chemical name*. N′-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications*. Melting point range of 180° C to 186° C.

(c) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter.

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

(e) *Conditions of use*. It is used for cattle as follows:

(1) *Amount*. 2.5 or 15 grams per tablet.

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

(ii) *Limitations*. Administer 25 milligrams per pound of animal weight per day for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use only by or on the order of a licensed veterinarian.

(2) *Amount*. 15-gram controlled release tablets.

(i) *Indications for use*. 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*); for

use prophylactically in cattle during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(ii) *Limitations*. Administer 100 milligrams per pound of body weight; do not treat within 16 days of slaughter; as sole source of sulfonamide; not for use in lactating dairy cows; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2260 Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) *Sponsor*. See No. 010042 in § 510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690 in § 510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.

(2) *Related tolerance in edible products*. See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer as a single dose 100 milligrams of sulfamethazine per pound of body weight the first day and 50 milligrams per pound of body weight on each following day.

(ii) *Indications for use*. For treatment of diseases caused by organisms susceptible to sulfamethazine.

(A) *Beef cattle and nonlactating dairy cattle*. Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis* and *Eimeria zurnii*).

(B) *Horses*. Treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus equi*), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations*. Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Not for use in lactating dairy animals. Do not treat cattle within 10 days of slaughter. Not to be used in horses intended for food.

(b)(1) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of 5-gram sulfamethazine bolus.

(2) *Related tolerances in edible products*. See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use*. Ruminating beef and dairy calves. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacilloosis) caused by *E. coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *F. necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *E. bovis* and *E. zurnii*.

(iii) *Limitations*. Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follows recomended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

[54 FR 15751, Apr. 19, 1989; 54 FR 19283, May 4, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 64 FR 66383, Nov. 26, 1999]

§ 520.2260b Sulfamethazine sustained-release boluses.

(a)(1) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine prolonged-release bolus.

(2) *Conditions of use*—(i) *Amount*. Depending on the duration of therapeutic levels desired, administer boluses as a single dose as follows: 3½ days—1 bolus (22.5 grams) per 200 pounds of body

weight; 5 days—1 bolus per 100 pounds of body weight.

(ii) *Indications for use.* Beef and nonlactating cattle for sustained treatment of shipping fever pneumonia caused or complicated by *Pasteurella multocida;* as an aid in the treatment of foot rot, mastitis, pneumonia, metritis, bacterial enteritis, calf diphtheria, and septicemia when caused or complicated by bacteria susceptible to sulfamethazine.

(iii) *Limitations.* Cattle that are acutely ill should be treated parenterally with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter for use of a 27-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 27 grams (1 bolus) for each 150 pounds of body weight as a single dose.

(ii) *Indications for use.* For nonlactating cattle for the treatment of infections caused by organisms sensitive to sulfamethazine such as hemorrhagic septicemia (shipping fever complex), bacterial pneumonia, foot rot, and calf diphtheria and as an aid in the control of bacterial diseases usually associated with shipping and handling of cattle.

(iii) *Limitations.* If no response within 2 to 3 days, reevaluate therapy; do not crush tablets; treated animals must not be slaughtered for food within 28 days after the latest treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter for use of a 32.1-gram sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 32.1 grams (1 bolus) per 200 pounds of body weight.[1]

(ii) *Indications for use.* For beef and nonlactating dairy cattle for the treatment of diseases caused by sulfamethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *E. coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, and acute mastitis and acute metritis caused by *Streptococcus* spp.)[1]

(iii) *Limitations.* After 72 hours, all animals should be reexamined for persistence of observable disease signs. If signs are present, consult a veterinarian. It is strongly recommended that a second dose be given to provide for an additional 72 hours of therapy, particularly in more severe cases. The dosage schedule should be used at each 72-hour interval. Animals should not receive more than 2 doses because of the possibility of incurring residue violations. This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision; *follow dosages carefully*. Fluid intake must be adequate at all times throughout the 3-day therapy, Do not use in lactating dairy cattle. Do not treat animals within 12 days of slaughter.

(d)(1) *Sponsor.* See 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine sustained release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer 1 bolus (22.5 grams) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use.* Beef and nonlactating dairy cattle for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), *bacterial pneumonia (Pasteurella* spp.), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), colibacillosis (bacterial scours) (*Escherichia coli*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.) and acute metritis (*Streptococcus* spp.).

[1] These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not inlcude effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(iii) *Limitations*. Cattle that are acutely ill should be treated by injection with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating diary cattle; if treated animals do not respond within 2 to 3 days, consult a veterinarian.

(e)(1) *Sponsor*. See No. 061133 in § 510.600(c) of this chapter for use of an 8.02-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. Administer 2 boluses (8.02 grams per bolus) per 100 pounds of body weight, as a single dose.

(ii) *Indications for use*. Administer orally to ruminating calves for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bacterial pneumonia (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), and calf diptheria (*Fusobacterium necrophorum*).

(iii) *Limitations*. For use in ruminating replacement calves only; 72 hours after dosing all animals should be reexamined for persistence of disease signs; if signs are present, consult a veterinarian; do not slaughter animals for food for at least 12 days after the last dose; this product has not been shown to be effective for nonruminating calves; exceeding two consecutive doses may cause violative tissue residue to remain beyond the withdrawal time; do not use in calves under 1 month of age or calves being fed an all milk diet.

(f)(1) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for use of a 30-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. Administer at the rate of 1 bolus (30 grams per bolus) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use*. Administer orally to beef cattle and nonlactating dairy cattle for the treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; bacterial pneumonia associated with *Pasteurell* spp.; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; acute mastitis and metritis caused by *Streptococcus* spp.

(iii) *Limitations*. For use in beef cattle and nonlactating dairy cattle only; if symptoms persist for 2 or 3 days after use, consult a veterinarian; do not slaughter animals for food for at least 8 days after the last dose; do not use in lactating dairy cattle; do not administer more than two consecutive doses.

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

(h)(1) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for use of an 8.25-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. Administer at the rate of 1 bolus (8.25 grams per bolus) per 50 pounds of body weight, as a single dose. If signs of disease are significantly reduced, it is recommended that a second dose be given to provide an additional 72 hours of therapy.

(ii) *Indications for use*. Administer orally to ruminating beef and dairy calves for treatment of the following diseases when caused by one or more of the listed pathogenic organisms susceptible to sulfamethazine: bacterial pneumonia associated with *Pasteurella* spp.; colibacillosis (bacterial scours) caused by *Escherichia coli;* coccidiosis caused by *Eimeria bovis* and *E. zurnii;* and calf diphtheria caused by *Fusobacterium necrophorum*.

(iii) *Limitations*. Do not use in calves to be slaughtered under 1 month of age or calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older. If symptoms persist after 3 days, consult a veterinarian. Do not administer more than 2 consecutive doses. Do not slaughter

animals for food for at least 8 days after the last dose. Do not crush bolus.

[46 FR 36132, July 14, 1981, as amended at 48 FR 18803, Apr. 26, 1983; 48 FR 32760, July 19, 1983; 49 FR 29057, July 18, 1984; 50 FR 49372, Dec. 2, 1985; 51 FR 30212, Aug. 25, 1986; 53 FR 40727, Oct. 18, 1988; 54 FR 14341, Apr. 11, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001]

§ 520.2260c Sulfamethazine sustained-release tablets.

(a) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of an 8-gram sulfamethazine sustained-release tablet.

(b) *Conditions of use*—(1) *Amount*. 8 grams (1 tablet) per 45 pounds of body weight as a single dose.

(2) *Indications for use*. In calves for sustained treatment of pneumonia caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli;* and calf diptheria caused by *Fusobacterium necrophorum*.

(3) *Limitations*. If there is no response within 2 to 3 days, reevaluate therapy. Do not crush tablets. 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.

[48 FR 26763, June 10, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996]

§ 520.2261 Sulfamethazine sodium oral dosage forms.

§ 520.2261a Sulfamethazine sodium drinking water solution.

(a) *Sponsors*. See Nos. 017800 and 010042 in § 510.600(c) of this chapter for use of a 12.5-percent sulfamethazine sodium solution.

(b) *Related tolerances in edible products*. See § 556.670 of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer in drinking water to provide: Cattle and swine 112.5 milligrams of sulfamethazine sodium per pound of body weight per day on the first day and 56.25 milligrams per pound of body weight on subsequent days; Chickens, 61 to 89 milligrams of sulfamethazine sodium per pound of body weight per day, and turkeys 53 to 130 milligrams of sulfamethazine sodium per pound of body weight per day, depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors.

(2) *Indications for use*. For treatment and control of diseases caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle*. Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine*. Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys*. In chickens for control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoeides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease, in chickens, medicate for 6 consecutive days; coccidiosis, in chickens and turkeys, medicate as in paragraph (c) of this section, then reduce amount of medication to one-half for 4 additional days.

(3) *Limitations*. Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Not for use in lactating dairy cattle. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and

turkeys must actually consume enough medicated water which provides the recommended dosages.

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982]

§ 520.2261b Sulfamethazine sodium soluble powder.

(a) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter for use of a soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Related tolerances in edible products.* See § 556.670 of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer in drinking water to provide: Chickens 58 to 85 milligrams of sulfamethazine sodium per pound of body weight per day; turkeys 50 to 124 milligrams of sulfamethazine sodium per pound of body weight per day; depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors. Administer to cattle and swine in drinking water, or as a drench, to provide 108 milligrams of sulfamethazine sodium per pound of body weight on the first day and 54 milligrams of sulfamethazine sodium per pound of body weight per day on the second, third, and fourth days of administration.

(2) *Indications for use.* For treatment and control of disease caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine.* Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoeides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease in chickens, medicate for 6 consecutive days; coccidiosis in chickens and turkeys, medicate as in paragraph (c) of this section for 2 days, then reduce drug concentration to one-half for 4 additional days.

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days prior to slaughter for food. Not for use in lactating dairy animals. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages.

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[47 FR 25322, June 11, 1982]

§ 520.2280 Sulfamethizole and methenamine mandelate tablets.

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the treatment of urinary

tract infections in dogs and cats such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. It is also used 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.

(2) It is administered at a dosage level of one tablet for each 20 pounds of body weight given three times per day. The drug should be given until all signs are alleviated. To reduce the possibility of a relapse, it is suggested that therapy be continued for a further period of a week to 10 days.

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

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 13561, Apr. 5, 1985]

§ 520.2320 Sulfanitran and aklomide in combination.

(a) *Chemical names.* (1) Sulfanitran: Acetyl-(*p*-nitrophenyl)-sulfanilamide.

(2) Aklomide: 2-Chloro-4-nitrobenzamide.

(b) *Specifications.* (1) Sulfanitran conforms to the following specifications:

(i) Melting point range: 260° C. to 261° C.

(ii) Assay (by sodium nitrite titration): 97 to 100.5 percent.

(iii) Moisture (Method No. 6.123, ''Toluene Distillation Method—Official Final Action'' in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed., 1980, p. 83. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201–3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001): Not more than 2.0 percent.

(iv) Molecular weight: 335.34.

(v) Soluble in 0.1*N* sodium hydroxide, reprecipitating unchanged on acidification.

(2) Aklomide conforms to the following specifications:

(i) Minimum melting point: 170° C.

(ii) Moisture content: Not to exceed 1.0 percent.

(iii) Purity: Not less than 98 percent on an anhydrous basis.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See §§ 556.30 and 556.680 of this chapter.

(e) *Conditions of use.* It is used in the drinking water of chickens as follows:

(1) *Amount.* 374–747 milligrams of sulfanitran with 477–954 milligrams of aklomide.

(2) *Indications for use.* As an aid in the treatment of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(3) *Limitations.* Administer for 2 days at 747 milligrams of sulfanitran per gallon and 954 milligrams of aklomide per gallon, followed by 5 days at 374 milligrams of sulfanitran per gallon and 477 milligrams of aklomide per gallon; do not treat birds over 6 weeks of age; do not administer within 5 days of slaughter; not for laying chickens.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 9396, Mar. 5, 1982; 54 FR 18280, Apr. 28, 1989; 55 FR 8460, Mar. 8, 1990]

§ 520.2325 Sulfaquinoxaline oral dosage forms.

§ 520.2325a Sulfaquinoxaline drinking water.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) To No. 050749 for use of a 25-percent sulfaquinoxaline soluble powder and a 20-percent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To No. 060594 for use of 3.44- and 12.85-percent sulfaquinoxaline sodium solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) To No. 046573 for use of a 31.92-percent sulfaquinoxaline solution (sodium and potassium salts) as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(4) No. 053501 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(b) *Related tolerances.* See § 556.685 of this chapter.

(c) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti*.

(ii) Administer at the 0.04 percent level for 2 or 3 days, skip 3 days then administer at the 0.025 percent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 percent level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(2) *Turkeys.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides*.

(ii) Administer at the 0.025 percent level for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(3) *Chickens and turkeys.* (i) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(ii) Administer at the 0.04 percent level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. If cholera has become established as the respiratory or chronic form, use feed medicated with sulfaquinoxaline. Poultry which have survived typhoid outbreaks should not be kept for laying house replacements or breeders unless tests show they are not carriers.

(4) *Cattle and calves.* (i) For the control and treatment of outbreaks of coccidiosis caused by *Eimeria bovis* or *E. zurnii*.

(ii) Administer at the 0.015-percent level for 3 to 5 days in drinking water medicated with sulfaquinoxaline solution.

(iii) In lieu of treatment as provided in paragraph (e)(4)(ii) of this section, administer 1 teaspoon of 25-percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations.* Consult a veterinarian or poultry pathologist for diagnosis. May cause toxic reactions unless the drug is evenly mixed in water at dosages indicated and used according to directions. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, cattle, and calves must actually consume enough medicated water which provides a recommended dosage of approximately 10 to 45 milligrams per pound per day in chickens, 3.5 to 55 milligrams per pound per day in turkeys, and approximately 6 milligrams per pound per day in cattle and calves depending on the age, class of animal, ambient temperature, and other factors. A withdrawal period has not been established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Make fresh drinking water daily.

[48 FR 3964, Jan. 28, 1983, as amended at 48 FR 26762, June 10, 1983; 55 FR 29843, July 23, 1990; 59 FR 28769, June 3, 1994; 59 FR 33197, June 28, 1994; 61 FR 24443, May 15, 1996; 61 FR 63711, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 65 FR 10705, Feb. 29, 2000]

§ 520.2325b Sulfaquinoxaline drench.

(a)–(b) [Reserved]

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

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Conditions of uses.* As a 25-percent sulfaquinoxaline soluble powder.

(1) For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zurnii*.

(2) Give one teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(f) *Limitations.* For control of outbreaks of disease, medication should be

initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[48 FR 3964, Jan. 28, 1983, as amended at 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications*. Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer one tablet orally per 4 pounds of body weight.[1]

(2) *Indications for use*. Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.[1]

(3) *Limitations*. Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.[1]

[43 FR 60895, Dec. 29, 1978]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications*. Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) *Sponsor*. See § 510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Administer orally; continue treatment until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 59365, Nov. 17, 1994; 63 FR 5255, Feb. 2, 1998]

§ 520.2345b Tetracycline tablets.

(a) *Specifications*. Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor*. For 100, 250, or 500 milligrams per tablet, see No. 000069 in § 510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992]

§ 520.2345c Tetracycline boluses.

(a) *Specifications*. Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(b) *Sponsors*. See No. 010042 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No. 000009 in § 510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.720 of this chapter.

(d) *Conditions of use*. *Calves*—(1) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations*. Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(iii) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use specified in paragraph (d)(1)(i) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Amount*. 10 milligrams per pound of body weight per day in two divided doses.

(i) *Indications for use*. Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, bacterial enteritis caused by *E. coli*, and salmonella organisms susceptible to tetracycline.

(ii) *Limitations*. Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline.

[57 FR 37328, Aug. 18, 1992]

§ 520.2345d Tetracycline hydrochloride soluble powder.

(a) *Sponsors*. The following sponsors listed in § 510.600(c) of this chapter hold approvals for the drug concentrations (i.e., grams of tetracycline hydrochloride per pound) and conditions of use indicated:

(1) 000010, 046573, 051259, 057561, and 059130 102.4 and 324 grams per pound as in paragraph (d) of this section.

(2) 000069, 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(3) 010042, 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) 046573, 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(b) *Related tolerances*. See § 556.720 of this chapter.

(c) [Reserved]

(d) *Conditions of use in drinking water*—(1) *Calves*—(i) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae (Hemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations*. Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for sponsor 010042 and within 5 days of treatment for sponsors 046573 and 000010; prepare a fresh solution daily; use as the sole source of tetracycline.

(2) *Swine*—(i) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae (Hemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations*. Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor 010042 and within 4 days of treatment for sponsors 046573 and 000010; prepare a fresh solution daily; use as the sole source of tetracycline.

(3) *Chickens*—(i) *Amount*. Chronic respiratory disease: 400 to 800 milligrams per gallon. Infectious synovitis: 200 to 400 milligrams per gallon.

(ii) *Indications for use*. Control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline.

(iii) *Limitations*. Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

(4) *Turkeys*—(i) *Amount*. For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use*. Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations*. Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

[59 FR 17693, Apr. 14, 1994, as amended at 59 FR 19133, Apr. 22, 1994; 62 FR 5319, Feb. 5, 1997; 62 FR 35076, June 30, 1997; 62 FR 46668, Sept. 4, 1997; 62 FR 55160, Oct. 23, 1997; 64 FR 37673, July 13, 1999]

§ 520.2345e Tetracycline oral liquid.

(a) *Specifications*. Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

(b) *Sponsor*. See No. 000069, in § 510.600(c) of this chapter for use of 25 or 100 milligrams per milliliter liquid in dogs as in paragraph (c)(1) of this section; see No. 000009 in § 510.600(c) of this chapter for use of 100 milligrams per milliliter liquid in dogs and cats as in paragraph (c)(2).

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *Escherichia coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations*. Administer orally; continue treatment until symptoms have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *National Academy of Sciences/National Research Council (NAS/NRC) status*. These conditions were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Dogs and cats*—(i) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use*. Treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations*. Administer orally; continue treatment until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.

(a) *Specifications*. Each capsule contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin.

(b) *Sponsor*. No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic per pound of body weight (1 capsule for each 6 pounds) every 12 hours.

(2) *Indications for use*. Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations*. Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment

should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.

(a) *Specifications*. Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin, or 180 milligrams of tetracycline hydrochloride and 180 milligrams of novobiocin.

(b) *Sponsor*. No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds).

(2) *Indications for use*. Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations*. Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

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

(a) *Specifications*. Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride, 60 milligrams of novobiocin, and 1.5 milligrams of prednisolone or 180 milligrams of tetracycline hydrochloride, 180 milligrams of novobiocin, and 4.5 milligrams of prednisolone.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic and 0.25 milligram of prednisolone per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds) every 12 hours for 48 hours. Treatment is to be continued with novobiocin and tetracycline alone at the same dose schedule for an additional 3 days or longer as needed.

(2) *Indications for use*. Treatment of acute and chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*, when it is necessary to initially reduce the severity of associated clinical signs.

(3) *Limitations*. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Administer for 48 hours only. Continue treatment if needed with tetracycline/novobiocin alone. The product is contraindicated in animals with tuberculosis, hyperadrenocorticalism, or peptic ulcers. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2362 Thenium closylate tablets.

(a) *Chemical name*. (N,N-Dimethyl-N-2-phenoxyethyl-N-2′-thenylammonium)-p-chlorobenzene-sulfonate.

(b) *Specifications*. Thenium closylate tablets contain thenium closylate equivalent to 500 milligrams thenium as base in each tablet.

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

(d) *Conditions of use*. (1) The tablets are administered orally to dogs as a single day treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms). Dogs weighing 10 pounds and over are administered 1 tablet as a single dose. Dogs

weighing 5 to 10 pounds are administered one-half tablet twice during a single day. All dosages are given for 1 day only. The treatment should be repeated after 2 or 3 weeks.

(2) Suckling puppies or recently weaned puppies weighing less than 5 pounds should not be treated with the drug. Animals that are severely infected, exhibiting evidence of intestinal hemorrhage, debilitation, and anemia, should be given supportive treatment.

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 53477, Dec. 7, 1976; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2380 Thiabendazole oral dosage forms.

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

(a) *Chemical name.* 2-(4-Thiazolyl)-benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* (1) See No. 017800 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (e)(1)(ii) of this section.

(2) See No. 050604 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e)(1)(ii) of this section.

(3) See No. 021930 in § 510.600(c) of this chapter for the sponsor of the usage provided for by paragraph (e)(2) of this section.

(d) *Related tolerances.* See § 556.730 of this chapter.

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

(1) *Horses*—(i) *Route of administration.* In feed, as a top dressing.

(*a*) *Amount.* 2 grams per 100 pounds of body weight.

(*b*) *Indications for use.* For control of large strongyles, small strongyles, pinworms, and threadworms (including members of the genera *Strongylus*, *Cyathostomum*, *Cylicobrachytus*, and related genera, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*, *Oxyuris*, and *Strongyloides*).

(*c*) *Limitations.* Add to the usual feed of horses mixed into that amount of the feed normally consumed at one feeding. Warning: Not for use in horses intended for food.

(ii) *Route of administration.* In feed.

(*a*) *Amount.* 2 grams per 100 pounds of body weight.

(*1*) *Indications for use.* For control of large and small strongyles, *Strongyloides*, and pinworms of the genera *Strongylus*, *Cyathostomum*, *Cylicobrachytus* and related genera, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*, *Oxyuris*, and *Strongyloides*.

(*2*) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(*b*) *Amount.* 4 grams per 100 pounds of body weight.

(*1*) *Indications for use.* For control of ascarids of the genus *Parascaris*.

(*2*) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(2) *Cattle*—(i) *Route of administration.* In feed block.

(ii) *Amount.* 3.3 percent block consumed at the recommended level of 0.11 pound per 100 pounds of body weight per day.

(iii) *Indications for use.* For control of infections of gastrointestinal roundworms (*Trichostrongylus*, *Haemonchus*, *Ostertagia* and *Cooperia*).

(iv) *Limitations.* Administer to cattle on pasture or range accustomed to mineral protein block feeding for 3 days. Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or diagnostic laboratory prior to worming. Animals maintained under conditions of constant worm exposure may require re-treatment within 2 to 3 weeks. Animals that are severely parasitized, sick, or off feed should be isolated and a veterinarian consulted for advice concerning treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 62 FR 63271, Nov. 28, 1997]

§ 520.2380b Thiabendazole drench or oral paste.

(a) *Chemical name.* 2-(4-Thiazolyl) benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e) of this section.

(d) *Related tolerances.* See § 556.730 of this chapter.

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

(1) *Horses.* As a single liquid oral dose, administered as a drench or by stomach tube; or as an oral paste.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(*a*) *Indications for use.* For the control of infections of large strongyles (*Strongylus vulgaris, Strongylus endentatus*), small strongyles (*Cyathastomum, Cylicobrachytus* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum*), pinworms (*Oxyuris*), and threadworms (*Strongyloides*).

(*b*) *Limitations.* Not for use in horses to be slaughtered for food purposes. When administered by stomach tube, for use only by or on the order of a licensed veterinarian. When for use as a liquid oral drench or an oral paste, consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii) *Amount.* 4 grams per 100 pounds of body weight.

(*a*) *Indications for use.* For control of infections of ascardis (*Parascaris*).

(*b*) *Limitations.* Not for use in horses to be slaughtered for food purposes. When administered by stomach tube, use only by or on the order of a licensed veterinarian. When for use as a liquid oral drench or an oral paste, consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Pigs.* As an oral paste.

(i) *Amount.* 200 milligrams for each 5 to 7 pounds of body weight per dose.

(ii) *Indications for use.* For control of infections with *Strongyloides ransomi.* These infections are commonly found in Southeastern United States.

(iii) *Limitations.* Administer to baby pigs (1 to 8 weeks of age). Treatment may be repeated in 5 to 7 days if necessary. Before treatment, obtain an accurate diagnosis from a veterinarian or diagnostic laboratory. Do not treat within 30 days of slaughter.

(3) *Cattle.* Orally as a drench and in paste form using a dosing gun designed for the product.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*).

(*b*) *Limitations.* For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

(ii) *Amount.* 5 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of infections of *Cooperia spp.* or severe infections of other species in paragraph (e)(3)(i)(*a*) of this section.

(*b*) *Limitations.* For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

(4) *Sheep and goats.* Orally, as a drench.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms in sheep and goats. (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active

from 3 hours to 3 days following treatment against ova and larvae passed by sheep (good activity against *Trichostrongylus colubriformis* and *axei*, *Ostertagia spp.*, *Bunostomum spp.*, *Nematodirus spp.*, and *Strongyloides spp.;* less effective against *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations*. As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; in severe infections in sheep, treatment should be repeated in 2 to 3 weeks.

(5) *Goats*. Orally, as a drench.

(i) *Amount*. 3 grams per 100 pounds of body weight.

(ii) *Indications for use*. Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Cooperia spp.*, *Nematodirus spp.*, *Bunostomum spp.*, *Strongyloides spp.*, *Chabertia spp.*, and *Oesophagostomum spp.*).

(iii) *Limitations*. As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; treatment should be repeated in 2 to 3 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 41 FR 47424, Oct. 29, 1976; 62 FR 63271, Nov. 28, 1997]

§ 520.2380c Thiabendazole bolus.

(a) *Chemical name*. 2-(4-Thiazolyl) benzimidazole.

(b) *Specifications*. Conforms to N.F. XII.

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

(d) *Related tolerances*. See § 556.730 of this chapter.

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

(1) *Cattle*. In a bolus.

(i) *Amount*. 3 grams per 100 pounds of body weight.

(*a*) *Indications for use*. Control of infections of gastrointestinal roundworms (general *Trichostrongylus spp.*, *Haemonchus spp.*, *Nematodirus spp.*, *Ostertagia spp.*, and *Oesophagostomum radiatum*).

(*b*) *Limitations*. As a single oral dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount*. 5 grams per 100 pounds of body weight.

(*a*) *Indications for use*. Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp.*, *Haemonchus spp.*, *Nematodirus spp.*, *Ostertagia spp.*, and *Oesophagostomum radiatum*). Control of infections with *Cooperia spp*.

(*b*) *Limitations*. As a single oral dose; as a drench or bolus; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Sheep and goats*. In a bolus.

(i) *Amount*. 2 grams per 100 pounds of body weight.

(ii) *Indications for use*. Control of infections of gastrointestinal roundworms in sheep and goats (general *Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Cooperia spp.*, *Nematodirus spp.*, *Bunostomum spp.*, *Strongyloides spp.*, *Chabertia spp.*, and *Oesophagostomum spp.*); also active from 3 hours to 3 days following treatment against ova and larvae passed by sheep (good activity against *T. colubriformis* and *axei*, *Ostertagia spp.*, *Bunostomum spp.*, *Nematodirus spp.*, and *Strongyloides spp.;* less effective against *Haemonchus* contortus and *Oesophagostomum spp.*).

(iii) *Limitations*. As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; in severe infections in sheep, treatment should be repeated in 2 to 3 weeks.

(3) *Goats*. In a bolus.

(i) *Amount*. 3 grams per 100 pounds of body weight.

(ii) *Indications for use*. Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Cooperia spp.*, *Nematodirus spp.*, *Bunostomum spp.*, *Strongyloides spp.*,

Chabertia spp., and *Oesophagostomum spp.*).

(iii) *Limitations*. As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; treatment should be repeated in 2 to 3 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 62 FR 63271, Nov. 28, 1997]

§ 520.2380d Thiabendazole, piperazine citrate suspension.

(a) *Specifications*. Each fluid ounce of suspension contains 2 grams of thiabendazole and 2.5 grams of piperazine (from piperazine citrate).

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

(c) *Conditions of use*. (1) It is administered to horses by stomach tube or as a drench at the rate of 1 fluid ounce of suspension per 100 pounds of body weight for the control of large strongyles, small strongyles, pinworms, *Strongyloides* and ascarids (including members of the genera *Strongylus spp.*, *Cyathostomum spp.*, *Cylicobrachytus spp.* and related genera *Craterostomum spp.*, *Oesophagodontus spp.*, *Poteriostomum spp.*, *Oxyuris spp.*, *Strongyloides spp.*, and *Parascaris spp.*).

(2) Do not use in horses intended to be used for food purposes.

(3) For use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 520.2380e Thiabendazole with trichlorfon.

(a) *Specifications*. The drug contains 5 grams of thiabendazole with 4.5 grams of trichlorfon, or 20 grams of thiabendazole with 18 grams of trichlorfon.

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Used for the treatment and control of bots (*Gasterophilus spp.*), large strongyles (*Strongylus spp.*), small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*), pinworms (*Oxyuris spp.*, *Strongyloides spp.*), and ascarids (*Parascaris spp.*) in horses.

(2) 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.

(3) Do not re-treat more than once every 30 days, preferably every 6 to 8 weeks.

(4) Do not treat animals if sick or debilitated; less than 4 months of age; or mares in last month of pregnancy.

(5) Do not administer intravenous anesthetics, especially muscle relaxants, within 2 weeks of use.

(6) Not for animals intended for food use.

(7) Do not use within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(8) If the label bears directions for administration of the drug 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.

[40 FR 23071, May 28, 1975, as amended at 48 FR 48229, Oct. 18, 1983]

§ 520.2380f Thiabendazole, piperazine phosphate powder.

(a) *Specifications*. Each ounce of water dispersible powder contains 6.67 grams of thiabendazole and 8.33 grams of piperazine (as piperazine phosphate).

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

(c) *Conditions of use*—(1) *Amount*. 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight.

(2) *Indications for use*. Treatment of infections of large strongyles (genus *Strongylus)*, small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, and related genera *Craterostomum*, *Oesophagodontus*, *Poteriostomum)*, pinworms *(Oxyuris)*, threadworms *(Strongyloides)*, and ascarids *(Parascaris)* in horses.

(3) *Limitations*. 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 ½ ounce of water for each 100 pounds of body weight; or sprinkled over a small amount of daily feed. Not for animals

intended for food use. 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 diagonosis, treatment, and control of parasitism.''

[46 FR 18963, Mar 27, 1981, as amended at 46 FR 52330, Oct. 27, 1981; 62 FR 63271, Nov. 28, 1997]

§ 520.2455 Tiamulin soluble powder.

(a) *Specifications*. A water-soluble powder containing 45 percent tiamulin used to make a medicated drinking water containing 227 or 677 milligrams of tiamulin per gallon.

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

(c) *Related tolerances*. See § 556.738 of this chapter.

(d) *Conditions of use in swine*—(1) Amount. 3.5 milligrams of tiamulin per pound of body weight for 5 days.

(i) *Indications for use*. For treatment of swine dysentery associated with *Treponema hyodysenteriae* susceptible to tiamulin.

(ii) *Limitations*. Use for 5 consecutive days. Withdraw 3 days before slaughter. Prepare fresh water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water.

(2) *Amount*. 10.5 milligrams of tiamulin per pound of body weight for 5 days.

(i) *Indications for use*. For treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(ii) *Limitations*. Use for 5 consecutive days. Withdraw 7 days before slaughter. Prepare fresh water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin or salinomycin) as adverse reactions may occur.

[52 FR 15718, Apr. 30, 1987, as amended at 58 FR 14313, Mar. 17, 1993; 62 FR 35076, June 30, 1997]

§ 520.2456 Tiamulin liquid concentrate.

(a) *Specifications*. A liquid concentrate containing 12.3 percent tiamulin used to make a medicated drinking water containing 227 milligrams or 681 milligrams of tiamulin per gallon.

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

(c) *Related tolerances*. See § 556.738 of this chapter.

(d) *Conditions of use in swine*— (1) *Amount*. Dysentery: 3.5 milligrams of tiamulin per pound of body weight daily. Pneumonia: 10.5 milligrams of tiamulin per pound of body weight daily.

(2) *Indications for use*. For treatment of swine dysentery associated with *Treponema hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(3) *Limitations*. Use for 5 consecutive days. When a dose is 3.5 milligrams per pound of body weight daily, withdraw medication 3 days before slaughter. When a dose is 10.5 milligrams per pound of body weight daily, withdraw 7 days before slaughter. Prepare fresh medicated water daily. Not for use in swine over 250 pounds body weight. Use as only source of drinking water. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, or salinomycin) as adverse reactions may occur.

[58 FR 14313, Mar. 17, 1993, as amended at 62 FR 35076, June 30, 1997]

§ 520.2460 Ticarbodine oral dosage forms.

§ 520.2460a Ticarbodine tablets.

(a) *Specifications*. Ticarbodine tablets, veterinary contain 90, 225, or 900 milligrams of ticarbodine per tablet.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs for the removal of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(2) Dosage is administered at 45 milligrams of the drug per pound of body

weight in a single dose. Dosage may be repeated in 21 days.

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

§ 520.2460b Ticarbodine capsules.

(a) *Specifications*. Each capsule contains 90, 225, 450, or 900 milligrams of ticarbodine.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs for removal of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum and Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum and Taenia pisiformis*).

(2) Dosage is administered orally as a single dose at 45 milligrams per lb. of body weight. Dosage may be repeated at 21-day intervals.

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

§ 520.2473 Tioxidazole oral dosage forms.

§ 520.2473a Tioxidazole granules.

(a) *Specifications*. Each gram of granules contains 200 milligrams of tioxidazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams per pound of body weight as a single dose.

(ii) *Indications for use*. Removal of mature large strongyles *(Strongylus edentatus, S. equinus,* and *S. vulgaris),* mature ascarids *(Parascaris equorum),* mature and immature (4th larval stage) pinworms *(Oxyuris equi),* and mature small strongyles *(Triodontophorus* spp.)

(iii) *Limitations*. For administration with feed: Sprinkle required amount of granules on a small amount of the usual grain ration and mix. Prepare for each horse individually. Withholding of feed or water not necessary. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[50 FR 52772, Dec. 26, 1985; 51 FR 2693, Jan. 21, 1986, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.2473b Tioxidazole paste.

(a) *Specifications*. Each plastic syringe contains 6.25 grams of tioxidazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams of tioxidazole per pound of body weight as a single dose.

(ii) *Indications for use*. Removal of mature large strongyles *(Strongylus edentatus, S. equinus,* and *S. vulgaris),* mature ascarids *(Parascaris equorum),* mature and immature (4th larval stage) pinworms *(Oxyuris equi),* and mature small strongyles *(Triodontophorus* spp.).

(iii) *Limitations*. Administer orally by inserting the nozzle of the syringe through the space between front and back teeth and deposit the required dose on the base of the tongue. Before dosing, make sure the horse's mouth contains no feed. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[52 FR 43059, Nov. 9, 1987]

§ 520.2481 Triamcinolone acetonide tablets.

(a) *Specifications*. Each tablet contains either 0.5 milligram or 1.5 milligrams of the drug.

(b) *Sponsor*. See Nos. 000010 and 053501 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use.* (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.

(2) An initial daily dosage of 0.05 milligram per pound of body weight is usually sufficient to control symptoms, although up to 0.1 milligram per pound of body weight may be given daily if response to the smaller dose is inadequate. As soon as feasible, and in any case within 2 weeks, dosage should be reduced gradually to maintenance levels of 0.0125 to 0.025 milligram per pound of body weight per day. Therapy should be discontinued by a gradual reduction in dosage after the condition has been controlled for several days. Therapy may be initiated with a single dose of sterile triamcinolone acetonide suspension veterinary in which case the tablet dosage should be administered beginning 5 to 7 days after the injection or when symptoms reappear.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter.

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

[40 FR 13838, Mar. 27, 1975, as amended at 51 FR 26002, July 18, 1986; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.2482 Triamcinolone acetonide oral powder.

(a) *Specifications.* Each 15 grams of triamcinolone acetonide oral powder contains 10 milligrams of triamcinolone acetonide.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use.* (1) The drug is used as an anti-inflammatory agent for horses.

(2) It is administered at a dosage of 0.005 to 0.01 milligram triamcinolone acetonide per pound of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Treatment may be initiated with a single dose of sterile triamcinolone acetonide suspension USP followed after 3 or 4 days with the use of triamcinolone acetonide oral powder.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter.

(4) Not for use in horses intended for food.

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

[41 FR 24884, June 21, 1976, as amended at 50 FR 41489, Oct. 11, 1985; 51 FR 26002, July 18, 1986]

§ 520.2520 Trichlorfon oral dosage forms.

§ 520.2520a Trichlorfon oral.

(a) *Chemical name.* Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(b) *Sponsor.* See No. 017800 in § 510.600(c) of this chapter.

(c) *Special considerations.* This drug is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Conditions of use.* (1) It is intended for use in horses for the removal of bots (*Gasterophilus spp.*), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equi*).

(2) Mix the drug, either dry or dissolved in water, in feed and administer at the rate of 4.5 grams of trichlorfon per 250 pounds of body weight. The drug is to be consumed at one feeding. Treatment should be repeated at 3-to 4-month intervals. Do not repeat treatment more frequently than every 30 days. Do not treat horses to be used for food. Do not treat sick or debilitated horses, colts under 4 months of age, mares in the last month of pregnancy, or animals other than horses. Do not administer intravenous anesthetics, especially muscle relaxants, for a period of 2 weeks after treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 63097, Nov. 2, 1979; 61 FR 34729, July 3, 1996]

§ 520.2520b Trichlorfon and atropine.

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

(2) For atropine: Atropine N.F.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.

(2) It is administered in distilled water as sole source of drinking water continuously for 7 to 14 days at 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter.

(3) Prepare fresh solution every 3 days. Do not use simultaneously with other drugs, insecticides, pesticides, or chemicals having cholinesterase activity, nor within 7 days before or after treatment with any other cholinesterase inhibitor.

(4) Restricted to use by or on the order of a licensed veterinarian.

§ 520.2520e Trichlorfon boluses.

(a) *Specifications*. Each bolus contains either 7.3, 10.9, 14.6, or 18.2 g of trichlorfon.

(b) *Sponsor*. See 000856 in § 510.600(c) of this chapter.

(c) *Special considerations*. Trichlorfon is a cholinesterase inhibitor. Do not use this product on animals simultaneously with, or within 2 weeks, before or after treatment with or exposure to, neuromuscular depolarizing agents (i.e., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *NAS/NRC status*. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(e) *Conditions of use*—(1) *Amount*. 18.2 milligrams per pound of body weight, except for strongyles use 36.4 milligrams per pound of body weight.

(2) *Indications for use*. For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations*. Do not fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48127, July 18, 1980]

§ 520.2520f Trichlorfon granules.

(a) *Specifications*. Each package contains either 18.2 or 36.4 g of trichlorfon.

(b) *Sponsor*. See 000856 in § 510.600(c) of this chapter.

(c) *Special considerations*. Trichlorfon is a cholinesterase inhibitor. Do not use this product on animals simultaneously with, or within 2 weeks before or after treatment with or exposure to neuromuscular depolarizing agents (i.e., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *NAS/NRC status*. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(e) *Conditions of use*—(1) *Amount*. 18.2 milligrams per pound of body weight.

(2) *Indications for use*. For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations*. Do not fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48128, July 18, 1980]

§ 520.2520g Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.

(a) *Specifications*. Each 54.10 grams (1.91 ounces) of water dispersible powder contains 9.10 grams of trichlorfon, 6.25 grams of phenothiazine, and the equivalent of 20.0 grams of piperazine base (as piperazine dihydrochloride).

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Special considerations*. Labeling shall bear the following statements:

The drug is a cholinesterase inhibitor. Do not use this product in horses simultaneously with, or within 2 weeks before or after treatment with, or exposure to, neuromuscular depolarizing agents (e.g., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount*. 18.2 milligrams of trichlorfon, 12.5 milligrams of phenothiazine, and 40.0 milligrams of piperazine base per pound of body weight.

(2) *Indications for use*. For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations*. Mix powder and vial contents together in warm water to form suspension. Administer by stomach tube. Do not fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 2757, Jan. 21, 1983]

§ 520.2582 Triflupromazine hydrochloride tablets.

(a) *Specifications*. Each tablet contains either 10 milligrams or 25 milligrams of triflupromazine hydrochloride.

(b) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs and cats to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.[1]

(2) The drug is administered orally to dogs and cats at a dosage level of 1 to 2 milligrams per pound of body weight daily; an initial dosage at the 2-milligrams level is suggested followed by daily doses at the 1-milligram level. Frequently, the drug may be withdrawn after 4 to 5 days, with drug effect continuing after withdrawal.[1]

(3) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.[1]

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2604 Trimeprazine tartrate and prednisolone tablets.

(a) *Specifications*. Each tablet contains: trimeprazine tartrate, 5 milligrams; and prednisolone, 2 milligrams.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is administered orally to dogs for the relief of itching regardless of cause; 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. It is also used in dogs 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. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.[1]

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.[1]

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.[1]

(4) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.[1]

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2605 Trimeprazine tartrate and prednisolone capsules.

(a) *Specifications*. Each capsule contains 3.75 milligrams of trimeprazine in sustained released form (as the tartrate) and 1 milligram of prednisolone (capsule no. 1) or 7.5 milligrams of trimeprazine in sustained release form (as the tartrate) and 2 milligrams of prednisolone (capsule no. 2).

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer either capsule orally once daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 2
Up to 10	1	.....
11 to 20	2	1
21 to 40	4	2
Over 40	6	3

(2) *Indications for use*. For the relief of itching regardless of cause, 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). It is also used in dogs as adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, tonsillitis, acute upper respiratory infections, and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(3) *Limitations*. After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained. Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 19367, Apr. 29, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications*. Each tablet contains 30 milligrams (5 milligrams of trimethoprim and 25 milligrams of sulfadiazine), 120 milligrams (20 milligrams of trimethoprim and 100 milligrams of sulfadiazine), 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine) or 960 milligrams (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine).

(b) *Sponsor*. See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) 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,

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

acute alimentary tract infections, wound infections, and abscesses.

(2) The drug is given orally at 30 milligrams per kilogram of body weight per day (14 milligrams per pound per day), or as follows:

Animal body weight (pounds)	Number of tablets
30 MG TABLETS	
2.2	1
4.4	2
6.6	3
8.8	4
120 MG TABLETS	
Up to 9	1
10 to 19	2
20 to 29	3
30 to 40	4
480 MG TABLETS	
30 to 40	1
40 to 60	1½
60 to 80	2
80 to 110	3
Over 110	4

(3) The drug is given once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis.

(4) Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

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

[41 FR 3853, Jan. 27, 1976, as amended at 44 FR 32214, June 5, 1979; 46 FR 23231, Apr. 24, 1981; 47 FR 36814, Aug. 24, 1982; 50 FR 9800, Mar. 12, 1985; 50 FR 11852, Mar. 26, 1985; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2611 Trimethoprim and sulfadiazine oral paste.

(a) *Specifications.* Each gram of oral paste contains 400 milligrams (67 milligrams of trimethoprim and 333 milligrams of sulfadiazine).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter for product to be dosed at 5 grams per 150 pounds of body weight per day. See No. 000061 in § 510.600(c) of this chapter for product to be dosed at 3.75 grams per 110 pounds of body weight per day.

(c) *Conditions of use*—(1) *Dosage.* (i) 5 grams (335 milligrams of trimethoprim and 1,665 milligrams of sulfadiazine) per 150 pounds (68 kilograms) of body weight per day. (ii) 3.75 grams (250 milligrams of trimethoprim and 1,250 milligrams of sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For horses where systemic anti-bacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) *Limitations.* Administer orally, once a day, as a single dose for 5 to 7 days; daily dose may also be halved and given morning and evening; for acute infection therapy continue treatment 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for prolonged use; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 34469, July 29, 1983, as amended at 49 FR 26714, June 29, 1984; 53 FR 11063, Apr. 5, 1988; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2612 Trimethoprim and sulfadiazine oral suspension.

(a) *Specifications.* Each milliliter of oral suspension contains 60 milligrams of drug (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine).

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

(c) *Conditions of use. Dogs*—(1) *Dosage.* 1 milliliter (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine) per 5 pounds of body weight.

(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*. For oral use only. Administer the recommended dose once daily or one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis. Do not treat for more than 14 consecutive days. During long-term treatment, a complete blood count is recommended. The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 19168, May 7, 1985, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2613 Trimethoprim and sulfadiazine powder.

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

(b) *Sponsor*. See No. 000009 and 058711 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses*—(1) *Dosage*. 3.75 grams of powder per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use*. For control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

(3) *Limitations*. Administer orally in a small amount of feed, as a single daily dose, for 5 to 7 days. Continue therapy for 2 to 3 days after clinical signs have subsided. If no improvement is seen in 3 to 5 days, reevaluate diagnosis. A complete blood count should be done periodically with prolonged use. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 36135, July 6, 1993, as amended by 64 FR 68289, Dec. 7, 1999]

§ 520.2640 Tylosin.

(a) *Specifications*. Tylosin is the antibiotic substance produced by growth of *Streptromyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled ''Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,'' which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations*. The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances*. See § 556.740 of this chapter.

(e) *Conditions of use*. It is used in drinking water of animals as follows:

(1) *Chickens*—(i) *Amount*. 2 grams per gallon.

(ii) *Indications for use*. Aid in the treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations*. Do not use in layers producing eggs for human consumption; administer from 1 to 5 days as sole source of drinking water; treated

chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter .

(2) *Turkeys*—(i) *Amount*. 2 grams per gallon.

(ii) *Indications for use*. Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations*. Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount*. 0.25 gram per gallon.

(ii) *Indications for use*. For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) *Limitations*. As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated: mix fresh solution daily; medication must be withheld from animals 48 hours prior to slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.

522.23 Acepromazine maleate injection.
522.44 Sterile sodium acetazolamide.
522.46 Alfaprostol.
522.56 Amikacin sulfate injection.
522.62 Aminopentamide hydrogen sulfate injection.
522.82 Aminopropazine fumarate sterile solution injection.
522.84 Beta-aminopropionitrile fumarate.
522.88 Sterile amoxicillin trihydrate for suspension.
522.90 Ampicillin implantation and injectible dosage forms.
522.90a Ampicillin trihydrate sterile suspension.
522.90b Ampicillin trihydrate for sterile suspension.
522.90c Ampicillin sodium for aqueous injection.
522.144 Arsenamide sodium aqueous injection.
522.147 Atipamezole hydrochloride.
522.150 Azaperone injection.
522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.
522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.
522.204 Boldenone undecylenate injection.
522.234 Butamisole hydrochloride.
522.246 Butorphanol tartrate injection.
522.311 Carfentanil citrate injection.
522.313 Ceftiofur sterile powder for injection.
522.314 Ceftiofur hydrochloride sterile suspension.
522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.
522.390 Chloramphenicol injection.
522.460 Cloprostenol sodium.
522.468 Colistimethate sodium powder for injection.
522.480 Repository corticotropin injection.
522.518 Cupric glycinate injection.
522.533 Deslorelin acetate.
522.535 Desoxycorticosterone pivalate.
522.536 Detomidine hydrochloride injection.
522.540 Dexamethasone injection.
522.542 Dexamethasone-21-isonicotinate suspension.
522.563 Diatrizoate meglumine and diatrizoate sodium injection.
522.575 Diazepam injection.
522.650 Dihydrostreptomycin sulfate injection.
522.690 Dinoprost tromethamine sterile solution.
522.723 Diprenorphine hydrochloride injection.
522.770 Doramectin.
522.775 Doxapram hydrochloride injection.
522.778 Doxycycline hyclate.
522.784 Doxylamine succinate injection.
522.800 Droperidol and fentanyl citrate injection.
522.812 Enrofloxacin solution.
522.820 Erythromycin injection.
522.840 Estradiol.
522.842 Estradiol benzoate and testosterone propionate in combination.
522.850 Estradiol valerate and norgestomet in combination.
522.863 Ethylisobutrazine hydrochloride injection.
522.883 Etorphine hydrochloride injection.
522.900 Euthanasia solution.
522.914 Fenprostalene solution.
522.940 Colloidal ferric oxide injection.