

§ 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 disacrylate.
- 520.154b Soluble bacitracin methylene disacrylate 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 capsules and tablets.
- 520.447 Clindamycin liquid.
- 520.452 Clenbuterol syrup.
- 520.455 Clomipramine hydrochloride tablets.
- 520.462 Clorsulon drench.
- 520.522 Cyclosporine.
- 520.530 Cythioate oral liquid.
- 520.531 Cythioate tablets.
- 520.534 Decoquinat.
- 520.538 Deracoxib.
- 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 Dicloxacin 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.
 520.955 Florfenicol.
 520.960 Flumethasone tablets.
 520.970 Flunixin oral dosage forms.
 520.970a Flunixin meglumine granules.
 520.970b Flunixin meglumine paste.
 520.1010 Furosemide.
 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.
 520.1195 Ivermectin liquid.
 520.1196 Ivermectin and pyrantel pamoate chewable tablets.
 520.1197 Ivermectin sustained-release bolus.
 520.1198 Ivermectin and praziquantel paste.
 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulгите suspension.
 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulгите tablets.
 520.1242 Levamisole hydrochloride oral dosage forms.
 520.1242a Levamisole powder for oral solution.
 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 [Reserved]
 520.1263c Lincomycin hydrochloride soluble powder.
 520.1265 Lincomycin and spectinomycin 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.
 520.1350 Meloxicam.
 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 Milbemycin oxime and 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 trilaminar cylinder/sheet.
 520.1451 Moxidectin.
 520.1452 Moxidectin gel.
 520.1453 Moxidectin and praziquantel gel.
 520.1468 Naproxen granules.
 520.1484 Neomycin sulfate soluble powder.
 520.1485 Neomycin sulfate oral solution.
 520.1498 Nitazoxanide paste.
 520.1510 Nitenpyram tablets.
 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.
 520.1855 Ponazuril.
 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.
 520.2098 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, diethylcarbazine 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 Sulfaethoxyppyridazine.
 520.2240a Sulfaethoxyppyridazine drinking water.
 520.2240b Sulfaethoxyppyridazine 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.

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- 520.2340 Tepoxalin.
- 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 Thienem cloylate 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.
- 520.2473 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.
- 520.2520b Trichlorfon and atropine.
- 520.2520e Trichlorfon boluses.
- 520.2520f Trichlorfon 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. 053501 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

¹These 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.