The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 172 approved new animal drug applications (NADAs) and 14 approved abbreviated new animal drug applications (ANADAs) for oral dosage form new animal drug products from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc. FDA is also amending the animal drug regulations to remove entries describing conditions of use for new animal drug products for which no NADA is approved, to make minor corrections, and to reflect a current format. This is being done to increase the accuracy and readability of the regulations.

**DATES:** This rule is effective May 20, 2014.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, steven.vaughn@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 E. 42d St., New York, NY 10017, and its wholly owned subsidiaries Alpharma, LLC; Fort Dodge Animal Health, Division of Wyeth; Fort Dodge Animal Health, Division of Wyeth Holdings Corp.; and its division, Pharmacia & Upjohn Co., have informed FDA that they have transferred ownership of, and all rights and interest in, the 172 approved NADAs and 14 approved ANADAs in table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 as follows:

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

<table>
<thead>
<tr>
<th>File No.</th>
<th>Product name</th>
</tr>
</thead>
<tbody>
<tr>
<td>006–707</td>
<td>SULQUIN (sulfadinoxine) 6–50 Soluble Powder.</td>
</tr>
<tr>
<td>006–891</td>
<td>SUL–Q–NO (sulfadinoxine) Liquid 34%.</td>
</tr>
<tr>
<td>007–879</td>
<td>TERRAMYCIN VET (oxytetracycline hydrochloride) Capsules.</td>
</tr>
<tr>
<td>007–981</td>
<td>SOXISOL (sulfadoxine) Tablets.</td>
</tr>
<tr>
<td>008–622</td>
<td>TERRAMYCIN (oxytetracycline hydrochloride) Soluble Powder.</td>
</tr>
<tr>
<td>009–339</td>
<td>CARAFEN (ammonium chloride and caraphen edisylate) Cough Syrup.</td>
</tr>
<tr>
<td>009–392</td>
<td>Primidone Tablets.</td>
</tr>
<tr>
<td>010–091</td>
<td>MYLEPSIN (primidone) Tablets.</td>
</tr>
<tr>
<td>011–060</td>
<td>TERRAMYCIN (oxytetracycline hydrochloride) Scour Tablets.</td>
</tr>
<tr>
<td>011–299</td>
<td>PARVEX (piperazine and carbon disulfide) Suspension.</td>
</tr>
<tr>
<td>011–315</td>
<td>NEOXIM 325 (neomycin sulfate) Soluble Powder.</td>
</tr>
<tr>
<td>011–403</td>
<td>MEDROL (methylprednisolone) Tablets.</td>
</tr>
<tr>
<td>011–482</td>
<td>VETAME (triflupromazine hydrochloride) Tablets.</td>
</tr>
<tr>
<td>011–580</td>
<td>VETAMOX (acetazolamide sodium) Soluble Powder.</td>
</tr>
<tr>
<td>011–590</td>
<td>PARVEX (piperazine and carbon disulfide) Bolus.</td>
</tr>
<tr>
<td>011–700</td>
<td>CORTABA (methylprednisolone and acetylsalicylic acid) Tablets.</td>
</tr>
<tr>
<td>012–437</td>
<td>TEMARIL–P (trimeprazine tartrate and prednisolone) Tablets.</td>
</tr>
<tr>
<td>012–656</td>
<td>Promazine Granules.</td>
</tr>
<tr>
<td>012–956</td>
<td>DYTREX (trichlorfon) Bolus, Capsules, Granules, Tablets.</td>
</tr>
<tr>
<td>013–201</td>
<td>DARBAZINE SPANSULE (prochlorperazine and isopropamide) Capsules.</td>
</tr>
<tr>
<td>013–248</td>
<td>Freed No. 10 or 25 (trichlorfon and atropine).</td>
</tr>
<tr>
<td>013–385</td>
<td>S.E.Z. (sulfadiazine) for Drinking Water 6.25%.</td>
</tr>
<tr>
<td>014–366</td>
<td>CYTOBIN (liothyronine sodium) Tablets.</td>
</tr>
<tr>
<td>015–102</td>
<td>ALBON (sulfadimethoxine) Tablets.</td>
</tr>
<tr>
<td>015–126</td>
<td>Specinomycin Tablet and Injection.</td>
</tr>
<tr>
<td>015–160</td>
<td>Sodium Sulfachlorpyrazine Solution.</td>
</tr>
<tr>
<td>015–250</td>
<td>WINSTROL–V (stanozoloin) Tablets.</td>
</tr>
<tr>
<td>030–137</td>
<td>MYLEPSIN (primidone) Tablets.</td>
</tr>
<tr>
<td>030–415</td>
<td>FLUCORT (flumethasone) Tablets.</td>
</tr>
<tr>
<td>030–416</td>
<td>MESULFIN (sulfamethizole and methenamine mandelate) Tablets.</td>
</tr>
<tr>
<td>031–205</td>
<td>AGRIBON (sulfadimethoxine) 12.5% Drinking Water Solution.</td>
</tr>
<tr>
<td>031–448</td>
<td>RHEAFORM (iodochlorhydroxyquin) Bolus.</td>
</tr>
<tr>
<td>031–553</td>
<td>ESB 3 (sodium sulfachlorpyrazine monohydrate) Solution and Soluble Powder.</td>
</tr>
<tr>
<td>031–715</td>
<td>ALBON (sulfadimethoxine) Boluses.</td>
</tr>
<tr>
<td>031–914</td>
<td>NEO–DARBAZINE SPANSULE (piperazine, isopropamide, and neomycin sulfate) Capsule.</td>
</tr>
<tr>
<td>032–738</td>
<td>PACITRAN (metoserpine hydrochloride).</td>
</tr>
<tr>
<td>032–946</td>
<td>MAGNA TERRAMYCIN (oxytetracycline hydrochloride and carbomycin) Soluble Powder.</td>
</tr>
<tr>
<td>033–149</td>
<td>PARVEX PLUS (piperazine, carbon disulfide, phenothiazine) Suspension.</td>
</tr>
<tr>
<td>033–342</td>
<td>PROBAN (cytioate) Tablets 30 mg.</td>
</tr>
<tr>
<td>033–606</td>
<td>PROBAN (cytioate) Oral Liquid.</td>
</tr>
<tr>
<td>033–653</td>
<td>S.E.Z. (sulfadiazine) Drinking Water Solution.</td>
</tr>
<tr>
<td>033–654</td>
<td>S.E.Z. (sulfadiazine) Obeles 15 G.</td>
</tr>
<tr>
<td>033–760</td>
<td>BLOAT GUARD (poloxalene) Drench Concentrate.</td>
</tr>
<tr>
<td>033–887</td>
<td>LINCOCE (lincomycin hydrochloride) Tablets.</td>
</tr>
<tr>
<td>035–161</td>
<td>TEMARIL–P SPANSULE (trimeprazine tartrate and prednisolone) Capsules.</td>
</tr>
<tr>
<td>035–650</td>
<td>DYREX (trichlorfon and atropine) Powder.</td>
</tr>
<tr>
<td>036–090</td>
<td>MAOLATE (chlorphenesin carbamate) Tablets.</td>
</tr>
<tr>
<td>039–356</td>
<td>TRAMISOL (levamisole hydrochloride) Cattle Wormer Bolus.</td>
</tr>
</tbody>
</table>
TABLE 1—NADAS AND ANADAS BEING TRANSFERRED FROM PFIZER, INC., TO ZOETIS, INC.—Continued

<table>
<thead>
<tr>
<th>File No.</th>
<th>Product name</th>
</tr>
</thead>
<tbody>
<tr>
<td>039–357</td>
<td>RIPERCOL L (levamisole hydrochloride) Soluble Drench Powder.</td>
</tr>
<tr>
<td>039–729</td>
<td>THERABLOAT (poloxalene) Oral Liquid.</td>
</tr>
<tr>
<td>040–587</td>
<td>LINCOGIN (lincomycin hydrochloride) Aquadrops.</td>
</tr>
<tr>
<td>041–629</td>
<td>Specinomycin Oral Liquid.</td>
</tr>
<tr>
<td>041–665</td>
<td>TRANVET (propionophenyl butyramide) Chewable Tablets.</td>
</tr>
<tr>
<td>042–548</td>
<td>AMFOROL (kanamycin sulfate, attapulgite, bismuth subcarbonate) Suspension.</td>
</tr>
<tr>
<td>042–740</td>
<td>TRAMISOL (levamisole hydrochloride) Soluble Drench Powder for Sheep.</td>
</tr>
<tr>
<td>042–837</td>
<td>TRAMISOL (levamisole hydrochloride) Sheep Wormer Oblets.</td>
</tr>
<tr>
<td>042–841</td>
<td>AMFOROL (kanamycin sulfate, attapulgite, bismuth subcarbonate) Oral Tablets.</td>
</tr>
<tr>
<td>042–888</td>
<td>PANMINTH/STRONGID (pyrantel tartrate) Pellets.</td>
</tr>
<tr>
<td>043–785</td>
<td>ALBON (sulfadimethoxine) Oral Suspension 5%.</td>
</tr>
<tr>
<td>045–513</td>
<td>RIPERCOL L (levamisole hydrochloride) Soluble Powder.</td>
</tr>
<tr>
<td>045–515</td>
<td>EQUIBUTE (phenylbutazone) Tablets 100 mg.</td>
</tr>
<tr>
<td>045–715</td>
<td>ROBAXIN–V (methylcarbamol) Tablets.</td>
</tr>
<tr>
<td>046–285</td>
<td>AGRIBON (sulfadimethoxine) Soluble Powder.</td>
</tr>
<tr>
<td>049–892</td>
<td>SPANBOLET II (sulfamethazine).</td>
</tr>
<tr>
<td>055–013</td>
<td>OMNIPEN (ampicillin anhydrous) Capsules 250 mg.</td>
</tr>
<tr>
<td>055–020</td>
<td>AUREOMYCIN (chlorotetracycline bisulfate) Soluble Powder.</td>
</tr>
<tr>
<td>055–032</td>
<td>DICLOXIN (dicloxacillin sodium monohydrate) Capsules.</td>
</tr>
<tr>
<td>055–042</td>
<td>AMPI–TAB (ampicillin trihydrate) Tablets.</td>
</tr>
<tr>
<td>055–047</td>
<td>CHLOROMYCETIN (chloramphenicol palmitate) Oral Suspension.</td>
</tr>
<tr>
<td>055–051</td>
<td>CHLOROMYCETIN (chloramphenicol) Tablets.</td>
</tr>
<tr>
<td>055–060</td>
<td>Penicillin G Potassium, USP.</td>
</tr>
<tr>
<td>055–073</td>
<td>PANMYCIN (tetracycline hydrochloride) Tablets.</td>
</tr>
<tr>
<td>056–074</td>
<td>AMPI–BOL (ampicillin trihydrate) Boluses.</td>
</tr>
<tr>
<td>056–076</td>
<td>ALBAPLEX (tetracycline hydrochloride novobiocin sodium) Tablets.</td>
</tr>
<tr>
<td>056–078</td>
<td>AMOXI–TABS (amoxicillin trihydrate) Tablets.</td>
</tr>
<tr>
<td>056–080</td>
<td>AMOXI–DOSER (amoxicillin trihydrate) Oral Suspension.</td>
</tr>
<tr>
<td>056–081</td>
<td>AMOXI–TABS (amoxicillin trihydrate) Tablets.</td>
</tr>
<tr>
<td>056–085</td>
<td>AMOXI–DROP (amoxicillin trihydrate) Oral Suspension.</td>
</tr>
<tr>
<td>056–086</td>
<td>AMOXI–BOL (amoxicillin trihydrate) Boluses.</td>
</tr>
<tr>
<td>056–088</td>
<td>AMOXI–SOL (amoxicillin trihydrate) Soluble Powder.</td>
</tr>
<tr>
<td>056–099</td>
<td>CLAVAMOX (amoxicillin trihydrate and clavulanate potassium) Tablets.</td>
</tr>
<tr>
<td>056–101</td>
<td>CLAVAMOX (amoxicillin trihydrate and clavulanate potassium) Drops.</td>
</tr>
<tr>
<td>065–004</td>
<td>PANMYCIN 500 (tetracycline hydrochloride) Bolus.</td>
</tr>
<tr>
<td>065–060</td>
<td>PANMYCIN AQUADROPS (tetracycline hydrochloride) Liquid.</td>
</tr>
<tr>
<td>065–066</td>
<td>TETRACHEL–VET (tetracycline hydrochloride) Tablets 100.</td>
</tr>
<tr>
<td>065–069</td>
<td>TETRACHEL–VET (tetracycline hydrochloride) Capsules 500.</td>
</tr>
<tr>
<td>065–090</td>
<td>DELTA ALBAPLEX (tetracycline hydrochloride, novobiocin sodium, prednisolone) Tablets.</td>
</tr>
<tr>
<td>065–099</td>
<td>ALBAPLEX (tetracycline hydrochloride and novobiocin sodium) Capsules.</td>
</tr>
<tr>
<td>065–107</td>
<td>ENTROMYCIN (bacitracin methylene disalicylate and streptomycin sulfate) Soluble Powder.</td>
</tr>
<tr>
<td>065–118</td>
<td>Tetracycline Vet (tetracycline hydrochloride) Capsules 250.</td>
</tr>
<tr>
<td>065–123</td>
<td>Tetracycline Soluble Powder.</td>
</tr>
<tr>
<td>065–140</td>
<td>TET–SOL 324 (tetracycline hydrochloride) Soluble Powder.</td>
</tr>
<tr>
<td>065–241</td>
<td>MYCHEL–VET (chloramphenicol) Capsules (50 mg).</td>
</tr>
<tr>
<td>065–270</td>
<td>POLYOTIC (tetracycline hydrochloride) Oblets.</td>
</tr>
<tr>
<td>065–280</td>
<td>FORTRACIN (bacitracin methylene disalicylate) Soluble.</td>
</tr>
<tr>
<td>065–313</td>
<td>BACIFERM 50 (bacitracin zinc) Soluble Powder.</td>
</tr>
<tr>
<td>065–409</td>
<td>PANMYCIN (tetracycline hydrochloride) Capsules.</td>
</tr>
<tr>
<td>065–410</td>
<td>TETRA–SAL (tetracycline hydrochloride).</td>
</tr>
<tr>
<td>065–441</td>
<td>POLYOTIC (tetracycline hydrochloride) Soluble Powder.</td>
</tr>
<tr>
<td>065–470</td>
<td>BMD (bacitracin methylene disalicylate) 50% Soluble Powder.</td>
</tr>
<tr>
<td>065–489</td>
<td>MYCHEL–VET (chloramphenicol) Tablets.</td>
</tr>
<tr>
<td>091–065</td>
<td>ROBIZONE–V (phenylbutazone) Tablets 100 mg.</td>
</tr>
<tr>
<td>091–076</td>
<td>GASTROGRAFIN (diatrizoate meglumine and diatrizoate sodium) Oral Solution.</td>
</tr>
<tr>
<td>091–079</td>
<td>STRONGID T (pyrantel pamoate) Oral Suspension.</td>
</tr>
<tr>
<td>092–237</td>
<td>RIPERCOL L-Piperazine (levamisole hydrochloride and piperazine dihydrochloride) Oral Solution.</td>
</tr>
<tr>
<td>093–105</td>
<td>ROBIZONE–V (phenylbutazone) Tablets 1 g.</td>
</tr>
<tr>
<td>093–512</td>
<td>DICOIDE (diethylcarbazine citrate) Tablets.</td>
</tr>
<tr>
<td>093–694</td>
<td>RIPERCOL L-Piperazine (levamisole hydrochloride and piperazine dihydrochloride) Soluble Powder.</td>
</tr>
<tr>
<td>093–903</td>
<td>RUMATEL (morantel tartrate) Cattle Wormer Bolus.</td>
</tr>
<tr>
<td>095–333</td>
<td>DIFOLIN (dichlorophene and toluene) Capsules.</td>
</tr>
<tr>
<td>095–411</td>
<td>ARQUEL (meclofenamic acid) Granules.</td>
</tr>
<tr>
<td>096–059</td>
<td>NBC Kaps Wormer (n-butyl chloride) Capsules.</td>
</tr>
<tr>
<td>096–674</td>
<td>EQUIPROXEN (naproxen) Granules.</td>
</tr>
<tr>
<td>100–094</td>
<td>Poultry Sulfa (sulfamerazine, sulfadoxine, sulfatoxazole) Soluble Powder.</td>
</tr>
<tr>
<td>100–237</td>
<td>NEMEX (pyrantel pamoate) Oral Suspension.</td>
</tr>
</tbody>
</table>
Accordingly, the Agency is amending the regulations in 21 CFR part 520 to reflect these transfers of ownership. Also, the regulations are being amended to make minor corrections and to reflect a current format. This is being done to increase the accuracy and readability of the regulations.

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

In addition, FDA has noticed that certain sections of part 520 contain entries describing conditions of use for new animal drug products for which no NADA is approved. These errors were introduced by the Agency during the 1992 recodification of the regulations for certifiable antibiotics (57 FR 37318, 1992).
(c) Conditions of use in dogs—(1) **Amount.** Administer orally at a dosage of 5 to 15 milligrams per pound of body weight daily.

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

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

§ 520.38a [Amended]

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

§ 520.38b [Amended]

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

7. Revise § 520.62 to read as follows:

§ 520.62 Aminopentamide.

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

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

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

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

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

8. Revise § 520.82 to read as follows:

§ 520.82 Aminopropazine oral dosage forms.

9. Revise § 520.82a to read as follows:

§ 520.82a Aminopropazine.

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

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

(c) **Conditions of use in dogs and cats—(1) Amount.** Administer orally at a dosage of 1 to 10 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

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

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

10. Revise § 520.82b to read as follows:

§ 520.82b Aminopropazine and neomycin.

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

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

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

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

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

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

§ 520.88a Amoxicillin trihydrate film-coated tablets.

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

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

(c) * * *

(1) * * *

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

* * * * * * *

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

(2) * * *

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

* * * * * * *

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

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

§ 520.88b Amoxicillin trihydrate for oral suspension.

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

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

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

§ 520.88c Amoxicillin trihydrate oral suspension.

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

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

(d) Conditions of use in swine—(1) Amount. Administer 40 mg orally twice a day using a dosing pump. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days.

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

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

§ 520.88d Amoxicillin trihydrate soluble powder.

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

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

(d) Conditions of use in preruminating calves including veal calves—(1) Amount. Administer 400 mg per 100 pounds of body weight twice daily by drench or in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

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

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

§ 520.88e Amoxicillin trihydrate boluses.

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

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

(d) Conditions of use in cattle—(1) Amount. Administer 400 mg per 100 pounds of body weight twice daily. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

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

16. Revise § 520.88f to read as follows:

§ 520.88f Amoxicillin trihydrate tablets.

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

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

(c) Conditions of use in dogs—(1) Amount. Administer 5 mg per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Maximum duration of treatment should not exceed 30 days.

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

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

§ 520.88h Amoxicillin trihydrate and clavulinate potassium film-coated tablets.

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

(i) Amount. 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.90a [Reserved]

§ 520.90b Ampicillin tablets.

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

(b) Conditions of use in dogs—

(1) No. 055529 for use as in paragraph (d)(1) of this section.

(2) No. 054771 for use as in paragraph (d)(2) of this section.

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

■ 20. In § 520.90b, revise the section heading, paragraph (b), paragraph (c) heading, and paragraph (c)(3) to read as follows:

§ 520.90c Ampicillin capsules.

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

(b) Conditions of use in swine—

(1) No. 055529 for use as in paragraph (d)(1) of this section.

(2) No. 054771 for use as in paragraph (d)(2) of this section.

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

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

§ 520.90d Ampicillin for oral suspension.

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

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

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

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

§ 520.90e Ampicillin for soluble powder.

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

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

(c) Conditions of use in dogs—

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

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

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

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

§ 520.90f Ampicillin boluses.

(a) Amount. Each bolus contains butorphanol tartrate equivalent to 1, 5, or 10 milligrams (mg) butorphanol base.

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

(c) Conditions of use in dogs—

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

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

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

§ 520.260 [Amended]

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

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

§ 520.300a Cambendazole suspension.

(a) Conditions of use in swine—

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

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

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

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

§ 520.300b Cambendazole pellets.

(a) Conditions of use in horses—

(1) Amount. Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount. For animals maintained on premises where re-infection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.
(2) **Indications for use.** For the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostrongylus, Cylindrobrahytus, Craterostomum, Oesophagodontus); roundworms (Parascaris); pinworms (Oxyuris); and threadworms (Strongyloides).

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

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

§ 520.300c **Cambendazole paste.**

* * *

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

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

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

§ 520.309 **[Amended]**

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

§ 520.310 **[Amended]**

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

§ 520.370 **[Amended]**

■ 36. In § 520.370, in paragraph (b), remove “000069 and 026637” and in its place add “026637 and 054771”.

§ 520.390a **[Amended]**

■ 37. In § 520.390a, in paragraph (b)(1)(ii), remove “000856” and in its place add “054771”; and remove paragraph (b)(1)(iii).

§ 520.390b **[Amended]**

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

§ 520.390c **[Amended]**

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

§ 520.420 **[Amended]**

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

§ 520.434 **[Amended]**

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

§ 520.441 **[Amended]**

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

§ 520.446 **[Amended]**

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

§ 520.447 **[Amended]**

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

§ 520.530 **[Amended]**

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

■ 46. Amend § 520.531 as follows:

a. Add paragraph (a);

b. Remove paragraph (c);

c. Designate paragraph (d) as paragraph (c); and

d. Revise paragraph (b) and newly redesignated paragraph (c)(3).

The addition and revision read as follows:

§ 520.531 **Cythioate tablets.**

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

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

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

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

(c) * * *

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

■ 47. In § 520.534, revise paragraph (a), and in paragraph (b), remove “046573” and in its place add “054771”.

The revision reads as follows:

§ 520.534 **Decoquinate.**

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

* * * * *

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

§ 520.540a **Dexamethasone powder.**

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

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

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

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

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

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

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

(a) * * *

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

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

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

(b) * * *
§ 520.540c Dexamethasone chewable tablets.
  * * * * *
  (c) Conditions of use in dogs—(1) Amount. Administer orally by free-choice feeding or crumbled over food 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is obtained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.
  (2) Indications for use. As an anti-inflammatory agent.
  (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

§ 520.563 Dexamethasone chewable tablets.
  * * * * *
  (c) Conditions of use in dogs and cats—(1) Amount. Administer orally 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. Administered rectally 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.
  (2) Indications for use. For radiography of the gastrointestinal tract.
  (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

§ 520.608a Dithiazanine. * * * * *
  (a) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
  (b) Conditions of use in dogs—(1) Amount. Administer orally 5 to 10 milligrams per pound of body weight, three times daily. In severe cases, up to 25 milligrams per pound of body weight three times daily.
  (2) Indications for use. For the treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to dicloxacillin.
  (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

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

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

§ 520.623a Dithiazanine powder. * * * * *
  (a) Specifications. Each tablespoon of powder contains 200 milligrams (mg) dithiazanine iodide.
  (b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.
  (c) Conditions of use in dogs—(1) Indications for use and amount. Administer orally by mixing in food as follows:
  (i) For large roundworms (Toxocara canis, Toxascaris leonina): 10 mg per pound (/lb) of body weight for 3 to 5 days;
  (ii) For hookworms (Ancylostoma caninum, Uncinia stenocephala) and whipworms (Trichuris vulpis): 10 mg/lb of body weight for 7 days;
  (iii) For Strongyloides (Strongyloides canis, Strongyloides stercoralis): 10 mg/lb of body weight for 10 to 12 days;
  (iv) For heartworm microfilariae (Dirofilaria immitis): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.
  (2) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.626a Dithiazanine oral dosage forms. * * * * *
  (a) Specifications. Each tablet contains 10, 50, 100, or 200 milligrams (mg) dithiazanine iodide.
  (b) Sponsor. See No. 054628 in § 510.600(c) of this chapter.
  (c) Conditions of use in dogs—(1) Indications for use and amount. Administer orally immediately after feeding as follows:
  (i) For large roundworms (Toxocara canis, Toxascaris leonina): 10 mg per pound (/lb) of body weight for 3 to 5 days;
  (ii) For hookworms (Ancylostoma caninum, Uncinia stenocephala) and whipworms (Trichuris vulpis): 10 mg/lb of body weight for 7 days;
  (iii) For Strongyloides (Strongyloides canis, Strongyloides stercoralis): 10 mg/lb of body weight for 10 to 12 days;
  (iv) For heartworm microfilariae (Dirofilaria immitis): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.
  (2) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.763c Dithiazanine and piperazine suspension. * * * * *
  (a) Specifications. Each milliliter of suspension contains 69 milligrams (mg) dithiazanine iodide and 83 mg piperazine base (as piperazine citrate).
  (b) Sponsor. See No. 054628 in § 510.600(c) of this chapter.
  (c) Conditions of use in horses— * * * * *
64. Amend § 520.784 by revising the section heading and paragraph (c) to read as follows:

§ 520.784 Doxylamine.

* * * * *

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

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

65. Revise § 520.804 to read as follows:

§ 520.804 Enalapril.

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

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

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

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

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

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

§ 520.816 Episprantel.

* * * * *

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

(c) Conditions of use in dogs—(1) Amount. Administer orally 0.5 to 1.0 mg of episprantel maleate per kilogram of body weight per day.

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

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

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

§ 520.823 Erythromycin.

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

* * * * *

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

(c) Conditions of use in dogs—(1) Amount. Administer orally 2 to 5 milligrams per pound of body weight once daily.

(2) Indications for use. As a tranquilizer.

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

68. Amend § 520.863 as follows:

§ 520.863 Ethylisobutrazine.

* * * * *

(c) Conditions of use in dogs—(1) Amount. Administer orally 15 to 25 mg per kilogram of body weight per day initially.

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

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

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

§ 520.870 Etodolac.

* * * * *

(c) Conditions of use in dogs—(1) Amount. Administer orally 10 to 15 mg per kilogram of body weight per day orally.

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

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

70. Revise § 520.903a to read as follows:

§ 520.903a Febantel paste.

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

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

(c) Conditions of use in horses—(1) Amount. Administer paste orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfestation is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) Specifications. Each gram of paste contains 455 milligrams of febantel.

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

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

§ 520.903b Febantel suspension.

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

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

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

(2) Specifications. Each gram of suspension contains 455 milligrams of febantel.

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

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

The revisions read as follows:

§ 520.903d Febantel and praziquantel paste.

* * * * *

(c) Conditions of use in horses—(1) Amount. Administer paste orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfestation is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) Specifications. Each gram of paste contains 455 milligrams of febantel.

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

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

§ 520.903e Febantel tablets.

* * * * *

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

(c) Conditions of use in horses—(1) Amount. Administer tablet orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfestation is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) Specifications. Each tablet contains 455 milligrams of febantel.

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

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

§ 520.960 Flumethasone.

* * * * *

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

(c) Conditions of use in horses—(1) Amount. Administer orally 1.0 to 2.0 milligrams per kilogram of body weight per day.

(2) Indications for use. As a glucocorticoid used for various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

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

75. Add § 520.1060 to read as follows:

§ 520.1060 Glucose and glycine.

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

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

(c) Conditions of use in horses—(1) Amount. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight). Administer by stomach tube or drench, or by mixing well into a portion of the normal grain ration. For animals maintained on premises where reinfestation is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.
phosphate, 0.5 gram citric acid anhydrous, 0.12 gram potassium citrate, 6.36 grams aminoacetic acid (glycine), and 44.0 grams glucose.

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

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

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

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

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

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

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

§520.1100 Criseofulvin.

* * * * *

(d) Conditions of use in cattle—(1) Amount. Administered one bolus per 500 pounds body weight (35 to 50 milligrams per kilogram of body weight). Retreat in 3 to 4 weeks.

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

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

77. Amend §520.1120a as follows:

(b) Redesignate paragraphs (b) through (f) as paragraphs (a) through (e), respectively; and

(c) Revise newly redesignated paragraphs (a) and (e).

The revisions read as follows:

§520.1120a Haloxon drench.

* * * * *

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

* * * * *

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

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

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

§520.1199 [Amended]

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

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

84. In §520.1204a, in paragraph (b)(2), remove “053501” and in its place add “054771”.

85. Revise §520.1242b to read as follows:

§520.1242b Levamisol boluses or oblets.

(a) Specifications. Each bolus contains 2.19 grams levamisol hydrochloride. Each oplet contains 0.184 grams levamisol hydrochloride.

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

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

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

(e) Conditions of use—(i) Cattle—(1) Amount. Administer orally 2.19-gram boluses as a single dose as follows: 250 to 450 pounds, 1⁄2 bolus; 450 to 750 pounds, 1 bolus; and 750 to 1,050 pounds, 1 1/2 boluses.
§ 520.1242c Levamisol and piperazine.

86. Revise § 520.1242c to read as follows:

Levamisol hydrochloride and piperazine fluid ounce 0.45 gram of levamisole hydrochloride and piperazine constituted with water contains in each dihydrochloride equivalent to 5.0 grams levamisole hydrochloride.

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

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

§ 520.1242f Levamisol gel.

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

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

89. Amend § 520.1242g as follows:

(a) Remove paragraph (a);

(b) Redesignate paragraphs (b) through (f) as paragraphs (a) through (e); and

(c) Revise newly redesignated paragraph (d).

The revision reads as follows:

§ 520.1242g Levamisole resinate and famphur paste.

(a) Specifications. Each gram of paste contains either 25 or 50 milligrams of levamisole hydrochloride and 25 milligrams of mepacrine hydrochloride.

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

90. Revise § 520.1263a to read as follows:

§ 520.1263a Lincomycin tablets and syrup.

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

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

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

(2) Indications for use. An anthelmintic effective against infections of large strongyles (Strongyloss vulgaris, Streptococcus spp., Cylindrocyclus spp., Cylicodontophorus spp., Cylicostephanus spp., Cylicotetradon spp.), ascarids (Parasarcis equorum), and pinworms (Oxyuris equi).

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

§ 520.1265c [Amended]

91. In § 520.1263c, in paragraph (b)(1) remove “000009” and in its place add “046573” and in its place add “054771”.

§ 520.1284 Lithotyrronine.

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

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

(c) Conditions of use in dogs—(1) Amount. Administer orally to dogs at levels up to 12.8 μg per kilogram (kg) of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8 μg/kg of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

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

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

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

§ 520.1310 Marbofloxacin.

93. Revise § 520.1284 to read as follows:

§ 520.1320 Mebendazole.

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

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

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

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

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

(ii) Indications for use. For treatment of infections caused by large roundworms (Parasarcis equorum); large strongyles (Strongyloss vulgaris, S. equinus, S. vulgaris); small...
§ 520.1330 Meclofenamic acid granules.
(a) Specifications. Each gram of granules contains 5 milligrams (5 percent) meclofenamic acid.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in horses—(1) Amount. Administer 1 milligram per pound of body weight (1 gram per 1000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.
(2) Indications for use. For the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.
(3) Limitations. Do not use in horses intended for human consumption.

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

§ 520.1331 Meclofenamic acid tablets.
(a) Specifications. Each tablet contains 500 milligrams (mg) of meclofenamic acid.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs and cats—(1) Amount. Administer 60 mg per pound of body weight in two or three equally divided doses, followed each following day by 30 to 60 mg per pound of body weight, usually not to exceed 14 to 21 days.
(2) Indications for use. As an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1380 Methocarbamol.
(a) Specifications. Each tablet contains 50 milligrams (mg) of methocarbamol.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs and cats—(1) Amount. Administer 0.5 to 1 milligram per pound of body weight daily in divided doses 6 to 10 hours apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved.
(2) Indications for use. As an anti-inflammatory and analgesic agent.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1408 Methylprednisolone.
(a) Specifications. Each tablet contains 1, 2, or 4 milligrams (mg) of methylprednisolone.
(b) Sponsor. See sponsors in § 510.600(c) of this chapter.
(1) No. 054628 for use of 1- and 2-mg tablets;
(2) No. 054771 for use of 1- and 4-mg tablets.
(c) Conditions of use in dogs and cats—(1) Amount. 2.5 to 10 mg for dogs; 0.1 to 0.5 mg for cats; 0.25 mg for animals other than dogs and cats.
(2) Indications for use. As an anti-inflammatory agent.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.1450a [Amended]

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

§ 520.1450b [Amended]

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

§ 520.1450c [Amended]

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

§ 520.1451 [Amended]

110. In § 520.1451, in paragraph (b), remove “000069” and in its place add “054771”; remove paragraph (c); redesignate paragraph (d) as paragraph (c); and in newly redesignated paragraph (c)(3), remove the first sentence.

111. In § 520.1452, in paragraph (b), remove “000069” and in its place add “054771”; and revise paragraph (d)(3) to read as follows:

§ 520.1452 Moxidectin gel.

(d) * * *

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

112. In § 520.1453, in paragraph (b), remove “000069” and in its place add “054771”; and revise paragraph (d)(3) to read as follows:

§ 520.1453 Moxidectin and praziquantel gel.

(d) * * *

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

113. Revise § 520.1468 to read as follows:

§ 520.1468 Naproxen.

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

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

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

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

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

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

§ 520.1484 [Amended]

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

§ 520.1628 [Amended]

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

§ 520.1629 [Amended]

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

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

§ 520.1630 Oxibendazole suspension.

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

§ 520.1631 [Amended]

118. In § 520.1631, in paragraph (b), remove “000069” and in its place add “054771”.

119. Revise § 520.1638 to read as follows:

§ 520.1638 Oxibendazole.

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

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

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

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

(2) Suspension product described in paragraph (a)(2) of this section shall be labeled: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

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

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

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

§ 520.1640 [Removed]

120. Remove § 520.1640.

§ 520.1660a [Amended]

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

§ 520.1660b [Amended]

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

§ 520.1660c [Amended]

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

§ 520.1660d [Amended]

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

§ 520.1696b [Amended]

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

§ 520.1696c [Amended]

126. In § 520.1696c, in paragraph (a), remove “000069” and in its place add “054771”.

§ 520.1696d [Amended]


§ 520.1696e [Amended]

128. In § 520.1696e, remove “000069” and in its place add “054771”.

§ 520.1696f [Amended]

129. In § 520.1696f, in paragraph (b), remove “046573, 053501” and in its place add “054771.”
126. Amend § 520.1696c as follows:
   a. Remove paragraph (c);
   b. Redesignate paragraph (d) as paragraph (c); and
   c. Revise newly redesignated paragraph (c) heading and (c)(3).

The revisions read as follows:

§ 520.1696c Penicillin V powder.
   * * * * *
   (c) Conditions of use in dogs and cats—
   * * * * *
   (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

The revisions read as follows:

§ 520.1696d Penicillin V tablets.
   * * * * *
   (b) Sponsors. See Nos. 050604 and 054771 in § 510.600(c) of this chapter.
   (c) Conditions of use in dogs and cats—
   * * * * *
   (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1720a [Amended]

128. In § 520.1720a, in paragraph (b)(3), remove “000856” and in its place add “054771”.

129. Revise § 520.1720b to read as follows:

§ 520.1720b Phenylbutazone granules.
   (a) Specifications. Each package of granules contains 1 or 8 grams of phenylbutazone.
   (b) Sponsors. See sponsors in § 510.600(c) of this chapter.
   (1) No. 000061 for 8-gram package.
   (2) No. 059320 for 1-gram package.
   (c) Conditions of use in horses and ponies—(1) Amount. Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.
   * * * * *
   (2) Indications for use. For the treatment of inflammatory conditions associated with the musculoskeletal system.
   (3) Limitations. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

§ 520.1720c Phenylbutazone paste.
   * * * * *
   (c) * * *
   (3) Limitations. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

The revisions read as follows:

§ 520.1720d Phenylbutazone gel.
   * * * * *
   (c) * * *
   (3) Limitations. Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

The revisions read as follows:

§ 520.1802a Piperazine-carbon disulfide complex suspension.
   * * * * *
   (c) Conditions of use in horses and ponies—(1) Amount. Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.
   * * * * *
   (2) Indications for use. For the removal of large roundworms (Toxocara canis and Toxascaris leonina).
   (3) Limitations. Severely debilitated animals should not be treated except on the advice of a veterinarian.

§ 520.1804 [Amended]

135. Amend § 520.1803 as follows:
   a. Remove paragraph (c) wherever it appears.
   b. Redesignate paragraph (d) as paragraph (c);
   c. Revise newly redesignated paragraph (c) heading and (c)(3).

The revisions read as follows:

§ 520.1803 Piperazine citrate capsules.
   (a) Specifications. Each capsule contains piperazine citrate equivalent to 140 milligrams of piperazine base.
   * * * * *
   (c) Conditions of use in dogs and cats—(1) Amount. The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in 1/2 of the regular feeding and when the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfection may occur. Repeat treatment if indicated.
   (2) Indications for use. For the removal of large roundworms (Toxocara canis and Toxascaris leonina).
   (3) Limitations. Severely debilitated animals should not be treated except on the advice of a veterinarian.

§ 520.1804 [Amended]

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

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

§ 520.1805 Piperazine phosphate and thienium closylate tablets.
   * * * * *
   (c) * * *
   (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.1807 [Amended]
(a) In § 520.1807, in paragraph (b), remove “015565” and in its place add “No. 015565”.

§ 520.1840 [Amended]
(b) In § 520.1840. In paragraph (b)(1), remove “000069” and in its place add “054771”.

§ 520.1855 Ponazuril.
* * * * *
(c) * * * *
(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by order of a licensed veterinarian.

§ 520.1860 Pradofloxacin.
* * * * *
(c) * * * *
(3) Limitations. Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by order of a licensed veterinarian.

§ 520.1880 Prednisolone.
* * * * *
(c) Conditions of use in dogs—(1) Amount. Administer 2.5 milligrams per 4.5 kilograms (10 pounds) body weight per day. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

2) Indications for use. For use as an anti-inflammatory agent.
* * * * *
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

§ 520.1900 Primidone.
* * * * *
(b) Sponsor. See sponsor numbers in § 510.600(c) of this chapter.

§ 520.1920 Prochlorperazine and isopropamide.
(a) Specifications. Each capsule contains either:

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

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

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

§ 520.1921 Prochlorperazine.
* * * * *
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

§ 520.1962 Promazine.
(a) Specifications. Conforms to N.F. XII for promazine hydrochloride.

§ 520.2002 Propiopromazine.
(a) Specifications. Each chewable tablet contains 10 or 20 milligrams of propiopromazine hydrochloride.

§ 520.2043 [Amended]
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

§ 520.2044 [Amended]
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

§ 520.2045 Pyrantel tartrate powder.
(a) Specifications. Each gram of powder contains 106 milligrams (10.6 percent) or 113 milligrams (11.3 percent) pyrantel tartrate.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
§ 520.2098 Selegiline.

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

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

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

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

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

§ 520.2100 Selenium and vitamin E.

(a) Specifications. Each capsule contains:

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

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

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

(c) Conditions of use in dogs and cats—(1) Amount—(i) Dogs: Administer orally to small breeds, 1⁄2 to 1 tablet twice daily for several weeks; to large breeds, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

(ii) Cats: Administer orally 1⁄2 to 1 tablet twice daily for several weeks.

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

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

§ 520.2105a [Removed]

§ 520.2105b [Removed]

§ 520.2105 [Removed]

§ 520.2105a as [Redesignated as§ 520.2158]

§ 520.2158 [Removed]

§ 520.2158a [Removed]

§ 520.2158b [Removed]

§ 520.2158c [Removed]

§ 520.2123a Streptomycin.

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

(b) Sponsors. See Nos. 0000856, 000859, and 061623.

§ 520.2123c [Amended]

§ 520.2123c. In § 520.2123c in paragraph (b), remove “0000856, 000859, and 061623” and in its place add “0000859, 054771, and 061623”.

§ 520.2158 Stanozolol.

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

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

(c) Conditions of use in dogs and cats—(1) Amount—(i) Dogs: Administered orally to small breeds, 1⁄2 to 1 tablet twice daily for several weeks; to large breeds, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

(ii) Cats: Administer orally 1⁄2 to 1 tablet twice daily for several weeks.

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

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

§ 520.2150a [Removed]

§ 520.2150b [Removed]

§ 520.2150 [Removed]

§ 520.2150a as [Redesignated as§ 520.2158]
§ 520.2160 [Removed]

164. Remove § 520.2160.
165. Amend § 520.2170 as follows:

■ a. Revise the section heading;
■ b. Remove paragraph (d);
■ c. Redesignate paragraphs (b), (c), and (e) as paragraphs (c), (b), and (d), respectively; and
■ d. Revise newly redesignated paragraph (d) heading and paragraphs (d)(1) and (3).

The revisions read as follows:

§ 520.2170 Sulfabromomethazine.

* * * * *
(d) Conditions of use in cattle—(1) Amount. Administer 90 milligrams per pound body weight orally. Repeat in 48 hours if necessary
* * * * *
(3) Limitations. Milk taken from animals within 96 hours (8 milkings) of latest treatment must not be used for food. Do not administer within 18 days of slaughter.

166. Revise § 520.2184 to read as follows:

§ 520.2184 Sulfachloropyrazine.

(a) Specifications. Each gram of powder contains 476 milligrams of sodium sulfachloropyrazine monohydrate.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Related tolerance. See § 556.625 of this chapter.
(d) Conditions of use in chickens. It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:
   (1) Amount. Administer in drinking water as 0.03 percent solution for 3 days.
   (2) Indications for use. For the treatment of coccidiosis.
   (3) Limitations. Administer as sole source of drinking water and of sulfonamide medication. Withdraw 4 days prior to slaughter. Do not use in chickens producing eggs for human consumption.

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

§ 520.2200a Sulfadimethoxine solution and soluble powder.

(a) Specifications. (1) Each ounce of solution contains 3.75 grams (12.5 percent) sulfadimethoxine.
(2) Each 107 grams of powder contains the equivalent of 94.6 grams sulfadimethoxine as sulfadimethoxine sodium.
(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter:
   (1) Nos. 0000859, 054628, 054771, 054925, and 057561 for use of the product described in paragraph (a)(1) of this section.
   (2) Nos. 054771, 054925, 057561, 058829, 061623, and 066104 for use of the product described in paragraph (a)(2) of this section.
(c) Related tolerances. See § 556.640 of this chapter.
(d) Conditions of use—(1) Broiler and replacement chickens—(i) Amount. Administer 1.875 grams per gallon (0.05 percent) of drinking water for 6 consecutive days.
(ii) Limitations. For treatment of outbreaks of coccidiosis, fowl cholera, and infectious coryza.
(iii) Limitations. Do not administer to chickens over 16 weeks of age. As sole source of drinking water and sulfonamide medication. Withdraw 5 days before slaughter.
   (2) Turkeys—(i) Amount. Administer 0.938 grams per gallon (0.025 percent) of drinking water for 6 consecutive days.
(iii) Limitations. Do not administer to turkeys over 24 weeks of age. Use as the sole source of drinking water and sulfonamide medication. Withdraw 5 days before slaughter.
   (3) Cattle—(i) Amount. 1.18 to 2.36 grams per gallon (0.031 to 0.062 percent) of drinking water. As a drench, administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days. If no improvement within 2 to 3 days, reevaluate diagnosis. Do not treat beyond 5 days.
(ii) Indications for use. Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Fusobacterium necrophorum (Sphaerophorus necrophorus) sensitive to sulfadimethoxine.
(iii) Limitations. Withdraw 7 days before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

170. Revise § 520.2220b to read as follows:

§ 520.2220b Sulfadimethoxine suspension.

(a) Specifications. Each milliliter of suspension contains 50 milligrams (mg) sulfadimethoxine.
(b) Sponsors. See Nos. 000061 and 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs and cats—(1) Amount. Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily.
(2) Indications for use. For the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

171. Revise § 520.2220c to read as follows:

§ 520.2220c Sulfadimethoxine tablet.

(a) Specifications. Each tablet contains 125, 250, or 500 milligrams (mg) sulfadimethoxine.
(b) Sponsors. See Nos. 000061 and 054771 in § 510.600(c) of this chapter.
(c) Related tolerances. See § 556.640 of this chapter.
(d) Conditions of use in dogs and cats—(1) Amount. Administer 25 milligrams (mg) per pound of body weight on the first day followed by 12.5 milligrams (mg) per pound of body weight per day until the animal is free of symptoms for 48 hours.
(2) Indications for use. Treatment of sulfadimethoxine-susceptible bacterial infections.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

172. Revise § 520.2220d to read as follows:

§ 520.2220d Sulfadimethoxine bolus.

(a) Specifications. Each bolus contains 2.5, 5, or 15 grams sulfadimethoxine.
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Related tolerances. See § 556.640 of this chapter.
(d) Conditions of use in cattle—(1) Amount. Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.
(2) Indications for use. For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to
sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

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

173. Add §520.2220e to read as follows:

§ 520.2220e Sulfadimethoxine extended-release bolus.

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

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

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

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

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

174. Add §520.2220f to read as follows:

§ 520.2220f Sulfadimethoxine and *ormetoprim* tablet.

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

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

(c) Conditions of use in dogs—(1) Amount. On the first day of treatment, administer 25 mg per pound (55 mg per kilogram) of body weight. Then follow with a daily dosage of 12.5 mg per pound (27.5 mg per kilogram) of body weight. Do not exceed a total of 21 consecutive days.

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

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

175. Revise §520.2220g to read as follows:

§ 520.2220g Sulfadimethoxine extended-release solution.

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

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

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

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

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

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

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

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

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

§ 520.2240b Sulfaethoxypyridazine tablets.

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

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

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

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

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

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

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

176. Revise §520.2240b to read as follows:

§ 520.2240b Sulfaethoxypyridazine tablets.

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

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

(b) Sponsor. See No. 054771 in §510.600(c) of this chapter.
In § 520.2261b, revise paragraph (d)(3) to read as follows:

§ 520.2261b Sulfamethazine powder.
* * * * *  
(d) * * *  
(3) Limitations. Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

§ 520.2280 Sulfamethizole and methenamine.
* * * * *  
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs and cats—(1) Amount. Administer orally 1 tablet per 20 pounds of body weight 3 times per day until clinical signs are alleviated. To reduce the possibility of relapse, continue therapy for a week to 10 days.
(2) Indications for use. For treatment of urinary tract infections such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. As an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

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

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

The additions and revisions read as follows:

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

184. Revise § 520.2325b to read as follows:

§ 520.2325b Sulfadimethoxine drench.
(a) Specifications. A soluble powder containing 25 percent sulfadimethoxine.
(b) Sponsor. See No. 050749 in § 510.600(c) of this chapter.
(c) Conditions of use in cattle—(1) Amount. Administer 1 teaspoon of 25 percent sulfadimethoxine soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.
(2) Indications for use. For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by Eimeria bovis or E. zuernii.
(3) Limitations. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

§ 520.2330 [Amended]

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

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

§ 520.2345a Tetracycline capsules.
* * * * *  
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

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

§ 520.2345b Tetracycline tablets.
* * * * *  
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

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

§ 520.2345c Tetracycline boluses.
* * * * *  
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

189. Amend § 520.2345d as follows;

a. In paragraph (b)(1), remove “0000069” and in its place add “054771”;

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

c. Add paragraph (b)(5).

The addition reads as follows:

§ 520.2345d Tetracycline powder.
* * * * *  
(b) * * *  
(5) No. 000010: 25 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.
* * * * *

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

The revisions read as follows:

§ 520.2345e Tetracycline solution.
* * * * *  
(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

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

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.
* * * * *  
(c) Conditions of use in dogs—
* * * * *

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

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

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.
* * * * *
(c) **Conditions of use in dogs**—

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

193. In § 520.2345h, in paragraph (b), remove “000009” and in its place add “000001”; and revise the paragraph (c) heading and paragraph (c)(3) to read as follows:

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

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

194. Amend § 520.2362 as follows:

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

The revisions read as follows:

§ 520.2362 Thenium closylate.

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

(c) **Conditions of use in dogs**—(1) **Amount.** Dogs weighing over 40 pounds: Administer 1 tablet as a single dose. Dogs weighing 5 to 10 pounds: Administer one-half tablet twice daily during a single day. Repeat treatment after 2 or 3 weeks.

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

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

195. Amend § 520.2380a as follows:

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

The revision reads as follows:

§ 520.2380a Thiabendazole top dressing and mineral protein block.

(b) **Sponsors.** See sponsors in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

(1) No. 05401310 for use as in paragraph (d)(1)(i) of this section.

(2) No. 050664 for use as in paragraph (d)(1)(iii) of this section.

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

196. Amend § 520.2380b as follows:

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

The revisions read as follows:

§ 520.2380b Thiabendazole drench or paste.

(b) **Sponsor.** See No. 050664 in § 510.600(c) of this chapter.

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

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

§ 520.2380d Thiabendazole and piperazine citrate.

(c) **Conditions of use in horses**—(1) **Amount.** Administer 1 ounce of suspension per 100 pounds of body weight by stomach tube or as a drench.

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

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

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

§ 520.2380e Thiabendazole and trichlorfon.

(c) **Conditions of use in horses**—(1) **Amount.** Administer 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight. Use a single oral dose. Administer as a drench or by stomach tube or as a drench, the label shall bear the statement “Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.”

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

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

§ 520.2380d Thiabendazole and piperazine phosphate.

(c) **Conditions of use in horses**—(1) **Amount.** 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight.

(2) **Indications for use.** 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.).

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

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

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

§ 520.2380d Thiabendazole and piperazine phosphate.

(c) **Conditions of use in horses**—(1) **Amount.** 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight.

(2) **Indications for use.** 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.).

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

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

§ 520.2380e Thiabendazole and trichlorfon.

(c) **Conditions of use in horses**—(1) **Amount.** Administer 2 grams of thiabendazole with 1.8 grams of trichlorfon per 100 pounds of body weight sprinkled on the animals’ usual daily ration of feed, or may be mixed in 5 to 10 fluid ounces of water and administered by stomach tube or drench.

(2) **Indications for use.** For the treatment and control of bots (Gasterophilus spp.), large strongyles (Strongylus spp.), small strongyles (genera Cyathostomum, Cylicobrachytus, Craterostomum, Oesophagodontus, Poteriostomum), pinworms (Oxyuris spp., Strongyloides spp.), and ascarids (Parascaris spp.).

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

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

§ 520.2380f Thiabendazole and piperazine phosphate.

(c) **Conditions of use in horses**—(1) **Amount.** 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight.

(2) **Indications for use.** 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.).

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

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

§ 520.2520e [Redesignated as § 520.2520b]

■ 203a. Redesignate § 520.2520e as § 520.2520b.

■ 203b. Amend newly redesignated § 520.2520b as follows:

a. Revise paragraph (b);

b. Remove paragraphs (c) and (d);

b. Add new paragraph (c) as follows:

(c) Conditions of use in horses—

(a) sponsor. See No. 054771 in § 510.600(c) of this chapter.

(b) Conditions of use in cats—

(i) Amount. Administer orally 1 mg daily.

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

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

■ 204b. Amend newly redesignated § 520.2520c as follows:

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

- (c) Conditions of use in horses—

- (1) Amount. Administer orally 1 mg per pound of body weight daily, followed by 1 mg daily.

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

- (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.

■ 205a. Redesignate § 520.2520g as § 520.2520d.

■ 205b. Amend newly redesignated § 520.2520d as follows:

- a. Revise paragraph (b);

- b. Remove paragraphs (c) and (d);

- c. Add new paragraph (c) as follows:

- (c) Conditions of use in dogs—

- (1) Amount. Administer orally 1 mg per pound of body weight daily, followed by 1 mg daily.

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

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

- d. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

- (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.

- e. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

- f. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

- g. Revise the newly redesignated paragraph (c) heading and paragraph (c)(3).

The revisions read as follows:

§ 520.2520b Trichlorfon boluses.

- * * * * *

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

- (c) Conditions of use in horses—

- * * * * *

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

§ 520.2520f [Redesignated as § 520.2520c]

■ 204a. Redesignate § 520.2520f as § 520.2520c.

■ 204b. Amend newly redesignated § 520.2520c as follows:

a. Revise paragraph (b);

b. Remove paragraphs (c) and (d);

c. Add new paragraph (c) as follows:

- Limitations.

§ 520.2520c Trichlorfon granules.

- * * * * *

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

- (c) Conditions of use in horses—

- * * * * *

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

§ 520.2520g [Redesignated as § 520.2520d]

■ 205a. Redesignate § 520.2520g as § 520.2520d.

■ 205b. Amend newly redesignated § 520.2520d as follows:

a. Revise paragraph (b);

b. Remove paragraphs (c) and (d);

c. Add new paragraph (c) as follows:

- Limitations.

§ 520.2520d Trichlorfon, phenothiazine, and piperazine.

- * * * * *

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

- (c) Conditions of use in horses—

- * * * * *

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

■ 206. Revise § 520.2582 to read as follows:

§ 520.2582 Triflupromazine.

- (a) Specifications. Each tablet contains 10 or 25 milligrams (mg) triflupromazine hydrochloride.

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

- (c) Conditions of use in horses and cats—

- (1) Amount. Administer orally 1 mg per pound of body weight daily, followed by 1 mg daily.

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

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

■ 207. Revise § 520.2604 to read as follows:

§ 520.2604 Trimeprazine and prednisolone tablets.

- (a) Specifications. Each tablet contains 5 milligrams (mg) trimeprazine tartrate and 2 mg prednisolone.

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

- (c) Conditions of use in dogs—

- (1) Amount. Administer orally 1 mg per pound of body weight daily, followed by 1 mg daily.

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

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

■ 208. Revise § 520.2605 to read as follows:

§ 520.2605 Trimethoprim and sulfadiazine tablets.

- (a) Specifications. Each tablet contains 7.5 milligrams (mg) trimethoprim in sustained release form (as trimethoprim tartrate) and 1 mg prednisolone (Capsule No. 1); or

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

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

- (c) Conditions of use in dogs—

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

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

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

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

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

- After 4 days, the dosage is reduced to approximately 1/2 the initial dosage or to an amount just sufficient to maintain remission of symptoms.

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

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

■ 209. Revise § 520.2610 to read as follows:

§ 520.2610 Trimethoprim and sulfadiazine tablets.

- (a) Specifications. Each tablet contains 30 milligrams (mg) (5 mg para...
trimethoprim and 25 mg sulfadiazine), 120 mg (20 mg trimethoprim and 100 mg sulfadiazine), 480 mg (80 mg trimethoprim and 400 mg sulfadiazine) or 960 mg (160 mg trimethoprim and 800 mg sulfadiazine).

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

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

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

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

§ 520.2611 Trimeprazine and sulfadiazine powder.

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

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

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

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


Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2013–0904]

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

AGENCY: Coast Guard, DHS.

TABLE 1

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| Charlie Begin Memorial Lobster Boat Races | • Event Type: Power Boat Race.  
  • Sponsor: Boothbay Harbor Lobster Boat Race Committee.  
  • Date: June 14, 2014.  
  • Time: 10:00 a.m. to 2:00 p.m.  
  • Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of John’s Island within the following points (NAD 83):
  43°50′44″N, 069°38′37″W.  
  43°50′54″N, 069°38′06″W.  
  43°50′49″N, 069°37′50″W.  
  43°50′00″N, 069°38′20″W. |

| Rockland Harbor Lobster Boat Races | • Event Type: Power Boat Race.  
  • Sponsor: Rockland Harbor Lobster Boat Race Committee.  
  • Date: June 15, 2014.  
  • Time: 10:00 a.m. to 3:00 p.m.  
  • Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of the Rockland Breakwater Light within the following points (NAD 83):
  44°05′59″N, 069°04′53″W.  
  44°05′43″N, 069°05′25″W.  
  44°05′50″N, 069°05′05″W. |

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce the events taking place throughout the Sector Northern New England Captain of the Port (COTP) Zone. This action is necessary to protect marine traffic and spectators from the hazards associated with powerboat races, regattas, boat parades, rowing and paddling boat races, swim events, and fireworks displays. During the enforcement period, no person or vessel may enter the Special Local Regulation area or Safety Zone without permission of the COTP.

DATES: The marine events listed in 33 CFR 100.120 and 33 CFR 165.171 will take place from June 14, 2014 through July 28, 2014, during the times and dates specified in Tables 1 and 2 below.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Elizabeth Gunn, U.S. Coast Guard, Sector Northern New England, Waterways Management Division, via telephone at 207–767–0398 or email at Elizabeth.V.Gunn@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local Regulations and Safety Zones listed in 33 CFR 100.120 and 33 CFR 165.171. These regulations will be enforced for the duration of each event, on or about the dates indicated in TABLES 1 and 2.