AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
4/3/2014	MA	Marshfield	Marshfield Muni—George Harlow Field.	4/7418	02/14/14	RNAV (GPS) RWY 6, Orig-A.
4/3/2014	MA	Marshfield	Marshfield Muni—George Harlow Field.	4/7419	02/14/14	RNAV (GPS) RWY 24, Orig.
4/3/2014	MA	Marshfield	Marshfield Muni—George Harlow Field.	4/7420	02/14/14	NDB RWY 24, Amdt 2A.
4/3/2014	MA	Marshfield	Marshfield Muni—George Harlow Field.	4/7421	02/14/14	NDB RWY 6, Amdt 4C.
4/3/2014	KS	Hutchinson	Hutchinson Muni	4/7745	02/21/14	ILS OR LOC RWY 13, Amdt 16C.
4/3/2014	KS	Hutchinson	Hutchinson Muni	4/7746	02/21/14	NDB RWY 13, Amdt 15A.
4/3/2014	WI	West Bend	West Bend Muni	4/7984	02/14/14	RNAV (GPS) RWY 31, Orig.
4/3/2014	WI	West Bend	West Bend Muni	4/7985	02/14/14	RNAV (GPS) RWY 13, Orig-A.
4/3/2014	WI	West Bend	West Bend Muni	4/7986	02/14/14	RNAV (GPS) RWY 24, Orig.
4/3/2014	WI	West Bend	West Bend Muni	4/7987	02/14/14	VOR RWY 24, Amdt 3B.
4/3/2014	WI	West Bend	West Bend Muni	4/7988	02/14/14	VOR RWY 13, Amdt 5B.
4/3/2014	WI	West Bend	West Bend Muni	4/7989	02/14/14	LOC RWY 31, Orig-C.
4/3/2014	WI	West Bend	West Bend Muni	4/7990	02/14/14	RNAV (GPS) RWY 6, Orig-A.
4/3/2014	FL	West Palm Beach	Palm Beach Intl	4/7998	02/19/14	ILS OR LOC RWY 28R, Amdt 3.
4/3/2014	FL	West Palm Beach	Palm Beach Intl	4/7999	02/19/14	RNAV (GPS) Y RWY 28R, Amdt 2.
4/3/2014	FL	West Palm Beach	Palm Beach Intl	4/8000	02/19/14	RNAV (GPS) Y RWY 32, Amdt 2.
4/3/2014	TN	Covington	Covington Muni	4/8323	02/14/14	Takeoff Minimums and (Obstacle) DP, Orig.
4/3/2014	NY	New York	Long Island Mac Arthur	4/8346	02/19/14	RNAV (GPS) RWY 6, Amdt 1.
4/3/2014	NY	New York	Long Island Mac Arthur	4/8347	02/19/14	RNAV (GPS) RWY 33L, Orig.
4/3/2014	NY	New York	Long Island Mac Arthur	4/8348	02/19/14	RNAV (GPS) RWY 24, Amdt 1A.
4/3/2014	NY	New York	Long Island Mac Arthur	4/8349	02/19/14	ILS OR LOC RWY 24, Amdt 4A.
4/3/2014	NY	New York	Long Island Mac Arthur	4/8350	02/19/14	RNAV (GPS) RWY 15R, Orig.
4/3/2014	ME	Auburn/Lewiston	Auburn/Lewiston Muni	4/8497	02/19/14	VOR/DME A, Amdt 1.
4/3/2014	ME	Auburn/Lewiston	Auburn/Lewiston Muni	4/8498	02/19/14	RNAV (GPS) RWY 22, Amdt 1.
4/3/2014	GA	Dublin	W H 'Bud' Barron	4/8502	02/21/14	RNAV (GPS) RWY 2, Orig.
4/3/2014	GA	Dublin	W H 'Bud' Barron	4/8504	02/21/14	RNAV (GPS) RWY 20, Orig.
4/3/2014	GA	Dublin	W H ''Bud' Barron	4/8505	02/21/14	ILS OR LOC RWY 2, Amdt 2A.
4/3/2014	GA	Fort Stewart (Hinesville).	Wright AAF (Fort Stewart)/ Midcoast Rgnl.	4/8873	02/19/14	RNAV (GPS) RWY 6L, Orig.
4/3/2014	PA	Lancaster	Lancaster	4/8874	02/21/14	VOR/DME RWY 31, Amdt 4A.
4/3/2014	PA	Lancaster	Lancaster	4/8875	02/21/14	VOR RWY 31, Amdt 16.
4/3/2014	PA	Lancaster	Lancaster	4/8876	02/21/14	VOR/DME RWY 26, Amdt 10.
4/3/2014	PA	Lancaster	Lancaster	4/8877	02/21/14	VOR/DME RWY 8, Amdt 6.
4/3/2014	PA	Lancaster	Lancaster	4/8878	02/21/14	VOR RWY 8, Amdt 21.
4/3/2014	MD	Ocean City	Ocean City Muni	4/9173	02/18/14	RNAV (GPS) RWY 14, Orig-D.
4/3/2014	MD	Cumberland	Greater Cumberland Rgnl	4/9215	02/21/14	RNAV (GPS) RWY 23, Orig-A.
4/3/2014	MD	Cumberland	Greater Cumberland Rgnl	4/9216	02/21/14	LOC/DME RWY 23, Amdt 6B.
4/3/2014	MD	Cumberland	Greater Cumberland Rgnl	4/9217	02/21/14	LOC A, Amdt 4.
4/3/2014	MI	Ann Arbor	Ann Arbor Muni	4/9257	02/21/14	RNAV (GPS) RWY 24, Amdt 2A.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9258	02/21/14	RNAV (GPS) RWY 36, Orig.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9259	02/21/14	RNAV (GPS) RWY 25, Orig.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9260	02/21/14	VOR/DME RWY 7, Amdt 1B.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9262	02/21/14	VOR RWY 25, Amdt 1.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9263	02/21/14	RNAV (GPS) RWY 7, Orig-B.
4/3/2014	NH	Lebanon	Lebanon Muni	4/9264	02/21/14	RNAV (GPS) RWY 18, Orig.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2014–N–0002]

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 104 approved new animal drug applications (NADAs) and 5 approved abbreviated new animal drug applications (ANADAs) for implantation or injectable 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 March 25, 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 East 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 104 approved NADAs and 5 approved ANADAs in table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 as follows:

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

File No.	Product name
006–103	FOLLUTEIN (chorionic gonadotropin) Veterinary.
006–281	INTRAGEL (gelatin and sodium chloride) Injectable Solution.
006–417	RECOVR (tripelennamine hydrochloride) Injectable Solution.
008–769	LIQUAMYCIN (oxytetracycline hydrochloride) Injectable Solution.
008–932	KEMITHAL L.A. (thialbarbitone sodium) Powder for Injection.
009–576	SYNOVEX S and SYNOVEX C (progesterone and estradiol benzoate) Implants.
010–809	SURITAL (thiamylal sodium) Injectable Solution.
010–865	FERREXTRAN 100 (iron dextran complex) Injection.
011–241	Promazine HCl Injectable Solution.
011–427	SYNOVEX H (estradiol benzoate and testosterone propionate) Implants.
011–482	VETAME (Triflupromazine Hydrochloride) Injectable Solution.
011–593	Solu-Delta Cortef (prednisolone sodium succinate) Powder for Injection.
011–644	FELAC (colloidal ferric oxide) Injection.
011–789	PREDEF 2X (isoflupredone acetate) Injectable Suspension.
011–879	RUBRAFER S–100 (iron dextran complex) Injection.
011–953	BIOSOL (neomycin sulfate) Injectable Solution.
012–204	DEPO–MEDROL (methylprednisolone acetate) Injectable Suspension.
013–146	LIQUAMYCIN (oxytetracycline hydrochloride and lidocaine) Injectable Solution.
015–126	Spectinomycin Tablet and Injection.
015–147	DARBAZINE (prochlorperazine and isopropamide) Injection.
030–414	FLUCORT (flumethasone) Injectable Solution.
030–844	WINSTROL–V (stanozolol) Injectable Suspension.
031–944	DYNAMYXIN (sulfomyxin) Injectable.
033–655	S.E.Z. (sulfaethoxypyridazine) Intravenous Solution.
034–025	LINCOCIN (lincomycin hydrochloride) Injectable Solution.
034–705	EQUIPOISE (boldenone undecylenate) Injection.
036–211	ANAPRIME (flumethasone) Injectable Suspension.
036–212	FLUOSMIN (flumethasone acetate) Injectable Suspension.
038–838	ROBAXIN–V (methocarbamol) Injectable.
039–204	PROTOPAM (pralidoxime chloride) Powder for Injection.
041–245	AGRIBON (sulfadimethoxine) Injection 40%.
041–836	KANTRIM 200 (kanamycin sulfate) Injection.
043–079	CENTRINE (aminopentamide hydrogen sulfate) Injectable.
043–304	KETASET (ketamine hydrochloride) Injection.
044–611	TALWIN–V (pentazocine lactate) Injection.
045–514	EQUIBUTE (phenylbutazone) Injection.
045–716	TRANVET (propiopromazine hydrochloride) Injectable Solution.
046–788	Oxytocin Injection.
046–789	CHLOROPENT (chloral hydrate, magnesium sulfate, and pentobarbital) Injection.
046–790	Sodium Thiopental Powder for Injection.
049–553	RIPERCOL L (levamisole phosphate) Injection.
049–948	AQUACHEL 100 (oxytetracycline hydrochloride) Injectable Solution. with lidocaine.
055–064	PRINCILLIN (ampicillin trihydrate) Injection.
055–066	PRINCILLIN (ampicillin trihydrate) Injection.
055–071	PRINCILLIN (ampicillin trihydrate) Injection.
055–079	AMPI–JECT (ampicillin trihydrate) Injectable Suspension.
055–084	AMP–EQUINE (ampicillin sodium) Powder for Injection.
055–089	AMOXI–INJECT (amoxicillin trihydrate) Injectable Suspension. (for Cattle).
055–091	AMOXI–INJECT (amoxicillin trihydrate) Injectable Suspension. (for Dogs and Cats).
065–087	LONGICIL Fortified (penicillin G benzathine and penicillin G procaine) Suspension.
065–130	CRYSTALLINE (penicillin G procaine) Injectable Suspension.
065–169	FLO–CILLIN (penicillin G benzathine penicillin G procaine) Injectable Suspension.
065–174	CRYSTALLINE (penicillin G procaine) Injectable Suspension.
065–463	MYCHEL–VET (chloramphenicol) Injection.
065–483	PFIZER–STREP (dihydrostreptomycin sulfate) Injection.
091–127	RACHELLE OXYVET (oxytetracycline hydrochloride) Injection.
091–192	RENOGRAFIN–76 (diatrizoate meglumine and diatrizoate sodium) Injection.
091–240	RENOVIST (diatrizoate meglumine and diatrizoate sodium) Injection.
092–116	KETASET Plus (ketamine hydrochloride, promazine hydrochloride, and aminopentamide hydrogen sulfate) Injection.
094–114	LIQUAMYCIN 100 (oxytetracycline hydrochloride) Injectable Solution.
096–675	EQUIPROXEN (naproxen) 10% Injectable Solution.

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

File No.	Product name
098–640	ROBIZONE (phenylbutazone) Injectable Solution. 20%.
099–402	AQUACHEL 100 (oxytetracycline hydrochloride) Injectable Solution.
100–202	PROSTIN F2 Alpha (dinoprost tromethamine) Injectable Solution.
100–254	SYNCHROCEPT (prostalene) Injectable Solution.
100–703	CARBOCAINE–V (mepivacaine hydrochloride) Injectable Solution.
101–777	ROBINUL–V (glycopyrrolate) Injectable.
102–437	TRAMISOL (levamisole phosphate) Injectable Solution.
102–990	TORBUTROL (butorphanol tartrate) Injection.
104–184	STYQUIN (butamisole hydrochloride) Injectable Solution.
106–111	TELAZOL (tiletamine hydrochloride and zolazepam hydrochloride) for Injection.
108–901	LUTALYSE (dinoprost tromethamine) Injectable Solution.
111–369	Dexamethasone Sterile Solution.
112–048	HYLARTIN V (hyaluronate sodium) Injection.
113–232	LIQUAMYCIN LA–200 (oxytetracycline hydrochloride) Injectable Solution.
128–549	BOVILENE (fenprostalene) Injection.
128–967	REPOSE (dibucaine hydrochloride and secobarbital sodium) Euthanasia Solution.
130–660	DEXACHEL (dexamethasone) Injection.
132–486	DI–TRIM (trimethoprim and sulfadiazine) 24% Injectable Suspension.
134–778	DI–TRIM (trimethoprim and sulfadiazine) 48% Injectable Suspension.
135–780	TORBUGESIC (butorphanol tartrate) Injection.
136–651	GUAILAXIN (guaifenesin) Powder for Injection.
138–903	PORCILENE (fenprostalene) Injection.
139–237	FACTREL (gonadorelin hydrochloride) Injection.
139–913	EQURON (hyaluronate sodium) Injection.
140–269	KETOFEN (ketoprofen) Injection.
140–338	NAXCEL (ceftiofur sodium) Sterile Powder for Injection.
140–890	EXCENEL RTU (ceftiofur hydrochloride) Injectable Suspension.
141–043	SYNOVEX Choice or SYNOVEX Plus (trenbolone acetate and estradiol benzoate) Implants.
141–047	TORBUGESIC–SA (butorphanol tartrate) Injection.
141–061	DECTOMAX (doramectin) Injectable Solution.
141–069	FIRST GUARD (colistimethate sodium) Sterile Powder.
141–077	ADSPEC (spectinomycin sulfate tetrahydrate) Sterile Solution.
141–189	PROHEART 6 (moxidectin) Injectable Suspension.
141–199	RIMADYL (carprofen) Injectable Solution.
141–207	ADVOCIN (danofloxacin) Injectable Solution.
141–209	EXCEDE (ceftiofur crystalline free acid) Injectable Suspension.
141–235	EXCEDE (ceftiofur crystalline free acid) Injectable Suspension. for Swine.
141–244	DRAXXIN (tulathromycin) Injectable Solution.
141–263	CERENIA (maropitant) Injectable Solution.
141–285	CONVENIA (cefovecin sodium) Powder for Injection.
141–288	EXCENEL (ceftiofur hydrochloride) Injectable Suspension.
141–303	PROPOCLEAR (propofol).
141–322	IMPROVEST (gonadotropin releasing factor-diphtheria toxoid conjugate) Injection.
200–109	VELENIUM (vitamin E and sodium selenite) Injection.
200–127	PROSPEC (spectinomycin sulfate tetrahydrate) Injectable Solution.
200–142	Flunixin Meglumine Solution.
200–274	Lincomycin Injectable Solution. 30%.
200–367	SYNOVEX T120, T40, or T80 (trenbolone acetate and estradiol) Implants.

Accordingly, the Agency is amending the regulations in 21 CFR part 522 to reflect these transfers of ownership. In addition, the regulations are being amended to make minor corrections and to reflect a current format. This is being done to increase the accuracy and readability of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In § 522.23, remove paragraphs (d) and (e); and revise paragraphs (b) and (c) to read as follows:

§ 522.23 Acepromazine.

* * * * *

(b) *Sponsors.* See Nos. 000010 and 000859 in § 510.600(c) of this chapter:

(c) *Conditions of use in dogs, cats, and horses*—(1) *Amount.* Dogs: 0.25 to 0.5 mg per pound (/lb) of body weight; Cats: 0.5 to 1.0 mg/lb of body weight; Horses: 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* For use as a tranquilizer and as a preanesthetic agent.

(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.

§ 522.44 [Removed]

■ 3. Remove § 522.44.

■ 4. Revise paragraph (b) of § 522.56 to read as follows:

§ 522.56 Amikacin.

* * * * *

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

* * * * *

■ 5. Revise § 522.62 to read as follows:

§ 522.62 Aminopentamide.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligram (mg) aminopentamide hydrogen sulfate.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by subcutaneous or intramuscular injection 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 animals weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use, dosage may be continued by oral administration of tablets.

(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.

■ 6. Revise § 522.82 to read as follows:

§ 522.82 Aminopropazine.

(a) *Specifications.* Each milliliter of solution contains aminopropazine fumarate equivalent to 25 milligrams (mg) aminopropazine base.

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

(c) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

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

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

(2) *Horses*—(i) *Amount.* Administer 0.25 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

(ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in colic spasms.

(iii) *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.

■ 7. Revise § 522.84 to read as follows:

§ 522.84 Beta-aminopropionitrile.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains 0.7 milligrams (mg) beta-aminopropionitrile fumarate.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 7 mg by intralesional injection every other day for five treatments beginning about 30 days after initial injury.

(2) *Indications for use in horses.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in horses where there is sonographic evidence of fiber tearing.

(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.

■ 8. Revise § 522.88 to read as follows:

§ 522.88 Amoxicillin.

(a) *Specifications*—(1) Each vial contains 3 grams (g) of amoxicillin trihydrate. Each milliliter of constituted suspension contains 100 or 250 milligrams (mg) amoxicillin trihydrate for use as in paragraph (d)(1) of this section.

(2) Each vial contains 25 g of amoxicillin trihydrate. Each milliliter of constituted suspension contains 250 mg amoxicillin trihydrate for use as in paragraph (d)(2) of this section.

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

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

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Administer 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use*—(A) *Dogs.* For treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis;* genitourinary infections (cystitis) due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis;* gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis;* bacterial dermatitis due to *S. aureus, Streptococcus* spp., and *P. mirabilis;* soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus, Streptococcus* spp., *E. coli,* and *P. mirabilis.*

(B) *Cats.* For treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli, Pasteurella* spp., and *P. mirabilis;* genitourinary infections (cystitis) due to *S. aureus, Streptococcus* spp., *E. coli, P. mirabilis,* and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella multocida.*

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

(2) *Cattle*—(i) *Amount.* Administer 3 to 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use.* For treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida, P. hemolytica, Haemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum.*

(iii) *Limitations.* Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 9. Revise § 522.90 to read as follows:

§ 522.90 Ampicillin injectable dosage forms.

■ 10. Revise § 522.90a to read as follows:

§ 522.90a Ampicillin trihydrate suspension.

(a) *Specifications.* (1) Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams (mg) of ampicillin.

(2) Each milliliter contains ampicillin trihydrate equivalent to 150 mg of ampicillin.

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

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraphs (d)(1), (d)(2), (d)(3)(i)(A), (d)(3)(ii)(A), (d)(3)(iii), and (d)(4) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in

paragraphs (d)(3)(i)(B), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

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

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* For enteritis: 3 mg per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 mg per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(ii) *Indications for use.* For treatment of bacterial enteritis in calves caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(iii) *Limitations.* Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 3 mg per pound of body weight by intramuscular injection, once or twice daily, for up to 3 days.

(ii) *Indications for use.* Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(iii) *Limitations.* Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs*—(i) *Amount*—(A) 3 to 6 mg per pound of body weight by intramuscular injection, once or twice daily. Usual treatment is 3 to 5 days.

(B) 3 to 5 mg of ampicillin per pound of body weight, once a day for up to 4 days.

(ii) *Indications for use*—(A) Treatment of respiratory tract infections due to *E. coli, Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli, Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(B) Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli, Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli,* when caused by susceptible organisms.

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

(4) *Cats*—(i) *Amount.* 5 to 10 mg per pound of body weight by intramuscular or subcutaneous injection, once or twice daily. Usual treatment is 3 to 5 days.

(ii) *Indications for use.* Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

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

■ 11. In § 522.90b, revise the section heading to read as follows:

§ 522.90b Ampicillin trihydrate powder for injection.

* * * * *

§ 522.90c [Amended]

■ 12. In paragraph (b) of § 522.90c, remove ''000069 and 010515'' and in its place add ''010515 and 054771''.

■ 13. Revise § 522.144 to read as follows:

§ 522.144 Arsenamide.

(a) *Specifications.* Each milliliter of solution contains 10.0 milligrams arsenamide sodium.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 milliliter (mL) per pound of body weight (1.0 mL for every 10 pounds) by intravenous injection twice a day for 2 days.

(2) *Indications for use.* For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis.*

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

■ 14. Revise § 522.161 to read as follows:

§ 522.161 Betamethasone.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Betamethasone acetate equivalent to 10.8 milligrams (mg) betamethasone and betamethasone disodium phosphate equivalent to 3 mg of betamethasone.

(2) Betamethasone dipropionate equivalent to 5 mg betamethasone and betamethasone sodium phosphate equivalent to 2 mg of betamethasone.

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

(1) No. 000061 for product described in paragraph (a)(1) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) No. 000061 for product described in paragraph (a)(2) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by intramuscular injection 0.25 to 0.5 milliliter (mL) per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of four injections.

(ii) *Indications for use.* As an aid in the control of pruritus associated with dermatoses.

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

(2) *Horses*—(i) *Amount.* Administer 2.5 to 5 mL by intra-articular injection.

(ii) *Indications for use*—(A) For the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpel and fetlock joints.

(B) As an aid in the control of inflammation associated with various arthropathies.

(iii) *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.

§ 522.204 [Amended]

■ 15. In paragraph (b) of § 522.204, remove ''053501'' and in its place add ''054771''.

■ 16. Revise § 522.234 to read as follows:

§ 522.234 Butamisole.

(a) *Specifications.* Each milliliter of solution contains 11 milligrams (mg) butamisole hydrochloride.

(b) *Sponsors.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 mg per pound of body weight by subcutaneous injection. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

(2) *Indications for use.* For the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

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

§ 522.246 [Amended]

■ 17. In paragraph (b)(1) of § 522.246, remove ''000856'' and in its place add ''054771''.

■ 18. In § 522.275, revise the section heading to read as follows:

§ 522.275 N-Butylscopolammonium.

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■ 19. Revise § 522.300 to read as follows:

§ 522.300 Carfentanil.

(a) *Specifications.* Each milliliter of solution contains 3 milligrams (mg) carfentanil citrate.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 5 to 20 micrograms per kilogram (0.005 to 0.020 mg per kilogram) of body weight into large muscle of the neck, shoulder, back, or hindquarter.

(2) *Indications for use.* For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations.* Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

§ 522.304 [Amended]

■ 20. In paragraph (b) of § 522.304, remove ''000069'' and in its place add ''054771''.

§ 522.311 [Amended]

■ 21. In paragraph (b) of § 522.311, remove ''000069'' and in its place add ''054771''.

§ 522.313a [Amended]

■ 22. In paragraph (b) of § 522.313a, remove ''000009'' and in its place add ''054771''.

§ 522.313c [Amended]

■ 23. In paragraph (b) of § 522.313c, remove ''000009, 000409, and 068330'' and in its place add ''000409, 054771, and 068330''.

■ 24. Revise § 522.380 to read as follows:

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate.

(a) *Specifications.* Each milliliter of solution contains 42.5 milligrams (mg) of chloral hydrate, 8.86 mg of pentobarbital, and 21.2 mg of magnesium sulfate.

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

(c) *Conditions of use*—(1) *Amount.* For general anesthesia: Administer 20 to 50 milliliters per 100 pounds of body weight by intravenous injection until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. As a sedative-relaxant: Administer at a level of one-fourth to one-half of the anesthetic dosage level.

(2) *Indications for use.* For general anesthesia and as a sedative-relaxant in cattle and horses.

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

■ 25. In § 522.390, revise the section heading and paragraphs (a), (b), and (c)(3) to read as follows:

§ 522.390 Chloramphenicol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams of chloramphenicol.

(b) *Sponsor.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) * * *

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

■ 26. Revise § 522.460 to read as follows:

§ 522.460 Cloprostenol.

(a) *Specifications.* Each milliliter of solution contains cloprostenol sodium equivalent to:

(1) 125 micrograms (µg) of cloprostenol; or

(2) 250 µg of cloprostenol.

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

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) of this section.

(2) Nos. 000061 and 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii), (c)(1)(iii), and (c)(2) of this section.

(c) *Conditions of use in cattle*—(1) *Amount and indications for use*—(i) Administer 375 µg by intramuscular injection to induce abortion in pregnant feedlot heifers from 1 week after mating until 4 1/2 months of gestation.

(ii) Administer 500 µg by intramuscular injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception; for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts; and for the treatment of pyometra.

(iii) Administer 500 µg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first, for scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

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

§ 522.468 [Amended]

■ 27. In paragraph (b) of § 522.468, remove ''046573'' and in its place add ''054771''.

■ 28. Revise § 522.480 to read as follows:

§ 522.480 Corticotropin.

(a) *Specifications.* Each milliliter of aqueous solution contains 40 or 80 U.S.P. (I.U.) units of repository corticotropin.

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

(1) No. 061623 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 026637 for use as in paragraph (c)(2) and (3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular injection.

(ii) *Indications for use.* As a diagnostic aid to test for adrenal dysfunction.

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

(2) *Dogs and cats*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular or subcutaneous injection, to be repeated as indicated.

(ii) *Indications for use.* For stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH).

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

(3) *Cattle*—(i) *Amount.* Administer 200 to 600 units by intramuscular or subcutaneous injection as an initial dose, followed by a dose daily or every other day of 200 to 300 units.

(ii) *Indications for use.* As a therapeutic agent for primary bovine ketosis; and for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

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

§ 522.522 [Amended]

■ 29. In paragraph (b) of § 522.522, remove ''000069'' and in its place add ''054771''.

■ 30. Amend § 522.535 as follows:

■ a. Redesignate paragraph (d) as paragraph (c);

■ b. Revise the section heading, and paragraphs (a) and newly designated (c)(1)(iii).

The revisions read as follows:

§ 522.535 Desoxycorticosterone.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of desoxycorticosterone pivalate.

* * * * *

(c) * * *

(1) * * *

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

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■ 31. Revise § 522.536 to read as follows:

§ 522.536 Detomidine.

(a) *Specification.* Each milliliter of solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required. For sedation, administer by intraveneous (IV) or intramuscular (IM) injection; for analgesia, administer by IV injection; for both sedation and analgesia, administer by IV injection.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(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. Amend § 522.540 as follows:

■ a. In paragraph (d)(2)(i), remove ''000069 and 000859'' and in its place add ''000859 and 054771'';

■ b. In paragraph (d)(2)(ii), remove ''000069'' and in its place add ''054771''; and

■ c. Revise the section heading and paragraphs (a)(3)(iii), (b)(1), (b)(3), (c)(1), (c)(3), (d)(1), (d)(3), (e)(1), and (e)(3).

The revisions read as follows:

§ 522.540 Dexamethasone solution.

(a) * * *

(3) * * *

(iii) *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.

(b)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

* * * * *

(3) *Conditions of use*—(i) *Amount.* Administer 0.25 to 1 mg by intravenous injection, repeated for 3 to 5 days or until a response is noted.

(ii) *Indications for use.* For use in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis.

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

(c)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

* * * * *

(3) *Conditions of use*—(i) *Amount.* Administer 2.5 to 5.0 mg by intravenous injection.

(ii) *Indications for use.* For use in horses as a rapid adrenal glucocorticoid and/or anti-inflammatory agent.

(iii) *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.

(d)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

* * * * *

(3) *Conditions of use*—(i) *Amount.* Administer by intravenous or intramuscular injection as follows:

(A) *Dogs:* 0.25 to 1 mg.

(B) *Cats:* 0.125 to 0.5 mg.

(C) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use.* For use in dogs, cats, and horses as an anti-inflammatory agent.

(iii) *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)(1) *Specifications.* Each milliliter of solution contains 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

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(3) *Conditions of use*—(i) *Amount.* Administer by intravenous injection as follows:

(A) *Dogs:* 0.25 to 1 mg; may be repeated for 3 to 5 days.

(B) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use.* For use in dogs and horses for glucocorticoid and anti-inflammatory effect.

(iii) *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.

■ 33. Revise § 522.542 to read as follows:

§ 522.542 Dexamethasone suspension.

(a) *Specifications.* Each milliliter of suspension contains 1 milligram (mg) of dexamethasone-21-isonicotinate.

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

(c) *Conditions of use*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs: 0.25 to 1 mg; cats: 0.125 to 0.5 mg; horses: 5 to 20 mg. Dosage may be repeated.

(2) *Indications for use.* For the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and 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.

■ 34. Revise § 522.563 to read as follows:

§ 522.563 Diatrizoate.

(a) *Specifications.* Each milliliter of solution contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* For excretion urography, administer 0.5 to 1.0 milliliter (mL) per pound of body weight to a maximum of 30 mL intravenously. For cystography, remove urine, administer 5 to 25 mL directly into the bladder via catheter. For urethrography, administer 1.0 to 5 mL via catheter into the urethra to provide desired contrasts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 mL directly into the heart via catheter or intraventricular puncture. For cerebral angiography, rapid injection of 3 to 10 mL via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography, rapidly inject 3 to 10 mL intravascularly into the vascular bed to be delineated. For lymphography, slowly inject 1.0 to 10 mL directly into the lymph vessel to be delineated. For arthrography, slowly inject 1.0 to 5 mL directly into the joint to be delineated. For discography, slowly inject 0.5 to 1.0 mL directly into the disc to be delineated. For sialography, slowly inject 0.5 to 1.0 mL into the duct to be delineated. For

delineation of fistulous tracts, slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias, inject 0.5 to 1.0 mL per pound of body weight directly into the peritoneal cavity.

(2) *Indications for use.* For visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiography, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography; and as an aid in delineating peritoneal hernias and fistulous tracts.

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

■ 35. In § 522.650, revise paragraphs (b), (c), (d)(1), and (d)(3) to read as follows:

§ 522.650 Dihydrostreptomycin sulfate injection.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.200 of this chapter.

(d) * * *

(1) *Amount.* Administer 5 milligrams per pound of body weight by deep intramuscular injection every 12 hours, for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination.

* * * * *

(3) *Limitations.* Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.690 [Amended]

■ 36. In paragraph (b) of § 522.690, remove ''000009'' and in its place add ''054771''.

■ 37. Revise § 522.723 to read as follows:

§ 522.723 Diprenorphine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams of diprenorphine hydrochloride.

(b) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(2) *Indications for use.* The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(3) *Limitations.* For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

§ 522.770 [Amended]

■ 38. In § 522.770, in paragraph (a), remove ''sterile aqueous''; and in paragraph (b), remove ''000069'' and in its place add ''054771''.

§ 522.778 [Removed]

■ 39. Remove § 522.778.

■ 40. Revise § 522.784 to read as follows:

§ 522.784 Doxylamine.

(a) *Specifications.* Each milliliter contains 11.36 milligrams (mg) of doxylamine succinate.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* Administer 25 mg per hundred pounds of body weight by intramuscular, subcutaneous, or slow intravenous injection.

(ii) *Dogs and cats:* Administer 0.5 to 1 mg per pound of body weight by intramuscular or subcutaneous injection. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect.

(2) *Indications for use.* For use in conditions in which 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.

■ 41. Revise § 522.800 to read as follows:

§ 522.800 Droperidol and fentanyl.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of droperidol and 0.4 mg of fentanyl citrate.

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

(c) *Conditions of use*—(1) *Amount.*

(i) For analgesia and tranquilization, administer as follows:

(A) 1 milliliter (mL) per 15 to 20 pounds (lbs) of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight; or

(B) 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight.

(ii) For general anesthesia, administer as follows:

(A) Administer 1 mL per 40 lbs of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight; or

(B) Administer 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight.

(2) *Indications for use.* As an analgesic and tranquilizer and for general anesthesia.

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

■ 42. In § 522.820, redesignate paragraphs (a) and (b) as paragraphs (b) and (a) respectively; and revise paragraphs (d)(1) introductory text, (d)(2) introductory text, and (d)(3) introductory text to read as follows:

§ 522.820 Erythromycin.

* * * * *

(d) * * *

(1) *Dog.* Administer product described in paragraph (a)(1) of this section as follows:

* * * * *

(2) *Cats.* Administer product described in paragraph (a)(1) of this section as follows:

* * * * *

(3) *Cattle.* Administer products described in paragraph (a) of this section as follows:

* * * * *

§ 522.842 [Amended]

■ 43. In paragraph (a)(1) of § 522.842, remove ''000856'' and in its place add ''054771''.

■ 44. Revise § 522.863 to read as follows:

§ 522.863 Ethylisobutrazine.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of ethylisobutrazine hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 2 to 5 mg per pound of body weight by intramuscular injection for profound tranquilization. Administer 1 to 2 mg per pound of body weight by intravenous injection to effect.

(2) *Indications for use.* For use as a tranquilizer.

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

■ 45. Revise § 522.883 to read as follows:

§ 522.883 Etorphine.

(a) *Specifications.* Each milliliter of solution contains 1 milligram of etorphine hydrochloride.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Special considerations.* Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

(d) *Conditions of use*—(1) *Amount.* Administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(2) *Indications for use.* For the immobilization of wild and exotic animals.

(3) *Limitations.* Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.900 [Amended]

■ 46. In paragraph (b)(2) of § 522.900, remove ''000856'' and in its place add ''054771''.

■ 47. Revise § 522.914 to read as follows:

§ 522.914 Fenprostalene.

(a) *Specifications.* (1) Each milliliter of solution contains 0.5 milligram (mg) fenprostalene.

(2) Each milliliter of solution contains 0.25 mg fenprostalene.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and for use of product described in paragraph (a)(2) as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.277 of this chapter.

(d) *Special considerations.* Labeling shall bear the following statements: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. It is readily absorbed through the skin and may cause abortion and/or bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(e) *Conditions of use*—(1) *Cattle*—(i) *Indications for use and amount*—(A) For feedlot heifers to induce abortion when pregnant 150 days or less, administer 1 mg (2 milliliter (mL)) subcutaneously.

(B) For beef or nonlactating dairy cattle for estrus synchronization, administer a single or two 1-mg (2-mL) doses subcutaneously, 11 to 13 days apart.

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

(2) *Swine*—(i) *Amount.* Administer a single injection of 0.25 mg (1 mL) subcutaneously.

(ii) *Indications for use.* For the induction of parturition in sows and gilts pregnant at least 112 days.

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

■ 48. Revise § 522.960 to read as follows:

§ 522.960 Flumethasone injectable dosage forms.

■ 49. Revise § 522.960a to read as follows:

§ 522.960a Flumethasone suspension.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of flumethasone.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 6 to 10 mg by intra-articular injection. Dosage is limited to a single injection per week in any one synovial structure.

(2) *Indications for use.* For use in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpitis, and osselets.

(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.

■ 50. Revise § 522.960b to read as follows:

§ 522.960b Flumethasone acetate solution.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) of flumethasone acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs weighing up to 10 pounds (lbs): 2 mg; dogs weighing 10 to 25 lbs: 4 mg; dogs weighing over 25 lbs: 8 mg. Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 mg per animal.

(2) *Indications for use.* For use in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

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

■ 51. Revise § 522.960c to read as follows:

§ 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) of flumethasone.

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

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

(1) *Horses*—(i) *Amount.* Administer 1.25 to 2.5 milligrams (mg) daily by intravenous, intramuscular, or intra-articular injection.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpitis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *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.

(2) *Dogs*—(i) *Amount.* Administer 0.0625 to 0.25 mg daily by intravenous, intramuscular, or subcutaneous injection; 0.125 to 1.0 mg daily by intra-lesional injection, depending on the size and location of the lesion; or 0.166 to 1.0 mg daily by intra-articular injection, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions

due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

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

(3) *Cats*—(i) *Amount.* Administer 0.03125 to 0.125 mg daily by intravenous, intramuscular, or subcutaneous injection.

(ii) *Indications for use.* For use in the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

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

§ 522.970 [Amended]

■ 52. In paragraph (b)(2) of § 522.970, remove ''000856'' and in its place add ''054771''.

■ 53. Revise § 522.995 to read as follows:

§ 522.995 Fluprostenol.

(a) *Specifications.* Each milliliter of solution contains fluprostenol sodium equivalent to 50 micrograms (µg) of fluprostenol.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.55 µg fluprostenol per kilogram of body weight by intramuscular injection.

(2) *Indications for use.* For use in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(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.

■ 54. In § 522.1010, revise paragraphs (d)(2)(i)(B) and (d)(2)(ii)(B) to read as follows:

§ 522.1010 Furosemide.

* * * * *

(d) * * *

(2) * * *

(i) * * *

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

(ii) * * *

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

* * * * *

■ 55. Revise § 522.1020 to read as follows:

§ 522.1020 Gelatin.

(a) *Specifications.* Each 100 milliliters contains 8 grams of gelatin in a 0.85 percent sodium chloride solution.

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

(c) *Conditions of use*—(1) *Amount.* The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight.

(2) *Indications for use.* For use to restore circulatory volume and maintain blood pressure in animals being treated for shock.

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

§ 522.1066 [Amended]

■ 56. In paragraph (b) of § 522.1066, remove ''Nos. 000856 and 000859'' and in its place add ''Nos. 000859 and 054771''.

§ 522.1081 [Amended]

■ 57. In paragraph (b)(1) of § 522.1081, remove ''053501'' and in its place add ''054771''.

§ 522.1083 [Amended]

■ 58. In paragraph (b) of § 522.1083, remove ''000069'' and in its place add ''054771''; and in paragraph (c)(3), remove the first two sentences.

■ 59. Revise § 522.1085 to read as follows:

§ 522.1085 Guaifenesin powder for injection.

(a) *Specifications.* The product is a sterile powder containing guaifenesin. A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution.

(b) *Sponsors.* See Nos. 037990 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milliliter of prepared solution per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a muscle relaxant.

(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.

■ 60. Revise § 522.1086 to read as follows:

§ 522.1086 Guaifenesin solution.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of guaifenesin and 50 mg of dextrose.

(b) *Sponsors.* See Nos. 000859 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milliliter per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a skeletal muscle relaxant.

(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.

§ 522.1125 [Amended]

■ 61. In paragraph (d)(3) of § 522.1125, remove the first two sentences.

■ 62. Amend § 522.1145 as follows:

■ a. In paragraph (a)(2), remove ''000009'' and in its place add ''054771'';

■ b. In paragraph (b)(2), remove ''053501'' and in its place add ''054771'';

■ c. Revise the section heading and paragraphs (a)(3)(i), (a)(3)(iii), (b)(3)(i), (b)(3)(iii), (c)(3), (d)(3)(iii), (f)(3)(i), and (f)(3)(iii).

The revisions read as follows:

§ 522.1145 Hyaluronate.

(a) * * *

(3) * * *

(i) *Amount.* Small and medium-size joints (carpal, fetlock): 20 mg; larger joint (hock): 40 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

* * * * *

(iii) *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.

(b) * * *

(3) * * *

(i) *Amount.* Small and medium-size joints (carpal, fetlock): 10 mg; larger joint (hock): 20 mg. Treatment may be repeated at weekly intervals for a total of four treatments.

* * * * *

(iii) *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.

(c) * * *

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock): 20 mg. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks.

(ii) *Indications for use.* For the intra-articular treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic, non-infectious synovitis associated with equine osteoarthritis.

(iii) *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.

(d) * * *

(3) * * *

(iii) *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.

* * * * *

(f) * * *

(3) * * *

(i) *Amount.* Small and medium-size joints (carpal, fetlock): 22 mg; larger joint (hock): 44 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

* * * * *

(iii) *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.

■ 63. In § 522.1150, remove footnote 1, and revise the section heading and paragraphs (a) and (c)(3) to read as follows:

§ 522.1150 Hydrochlorothiazide.

(a) *Specifications.* Each milliliter of solution contains 25 milligrams of hydrochlorothiazide.

* * * * *

(c) * * *

(3) *Limitations.* Milk taken from dairy animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 64. Revise § 522.1155 to read as follows:

§ 522.1155 Imidocarb powder for injection.

(a) *Specifications.* The product is a sterile powder containing imidocarb dipropionate. Each milliliter of constituted solution contains 100 milligrams (mg) of imidocarb base.

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

(c) *Special considerations.* Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to licensed or full-time State, Federal, or military veterinarians.

(d) *Conditions of use in horses and zebras*—(1) *Amount.* For *Babesia caballi* infections, administer 2 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage once after 24 hours. For *Babesia equi* infections, administer 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage four times at 72-hour intervals.

(2) *Indications for use.* For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia 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.

■ 65. Revise § 522.1156 to read as follows:

§ 522.1156 Imidocarb solution.

(a) *Specifications.* Each milliliter of solution contains 120 milligrams (mg) of imidocarb dipropionate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular injection. Repeat the dose after 2 weeks for a total of two treatments.

(2) *Indications for use.* For the treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

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

§ 522.1182 [Amended]

■ 66. In § 522.1182, in paragraph (b)(2), remove ''000856'' and in its place add ''054771''; and in paragraphs (b)(4) introductory text and (b)(5) introductory text, remove ''053501'' and in its place add ''054771.

■ 67. Add § 522.1185 to read as follows:

§ 522.1185 Isoflupredone.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of isoflupredone acetate.

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

(c) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use.* For use in the treatment of bovine ketosis. For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. 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 restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses and swine*—(i) *Amount*—(A) *Horses.* Administer 5 to 20 mg by intramuscular injection for systemic effect or by intrasynovial injection into a joint cavity, tendon sheath, or bursa for local effect.

(B) *Swine.* The usual dose for a 300-pound animal is 5 mg by intramuscular injection.

(ii) *Indications for use.* For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 68. Revise § 522.1204 to read as follows:

§ 522.1204 Kanamycin.

(a) *Specifications.* Each milliliter of solution contains 50 or 200 milligrams (mg) of kanamycin as kanamycin sulfate.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by subcutaneous or intramuscular injection 5 mg per pound of body weight per day in equally divided doses at 12-hour intervals.

(2) *Indications for use.* For the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

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

§ 522.1222 [Removed]

■ 69. Remove § 522.1222.

§ 522.1222a [Redesignated as § 522.1222 and Amended]

■ 70. Redesignate § 522.1222a as § 522.1222 and in newly designated § 522.1222, in paragraph (b), add ''054771,'' after ''054668,''.

§ 522.1222b [Redesignated as § 522.1223 and Revised]

■ 71. Redesignate § 522.1222b as § 522.1223 and revise it to read as follows:

§ 522.1223 Ketamine, promazine, and aminopentamide.

(a) *Specifications.* Each milliliter of solution contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity, 7.5 (mg) of promazine hydrochloride, and 0.0625 mg of aminopentamide hydrogen sulfate.

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

(c) *Conditions of use in cats*—(1) *Amount.* Administer by intramuscular injection 15 to 20 mg ketamine base per pound of body weight, depending on the effect desired.

(2) *Indications for use.* It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

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

■ 72. Revise § 522.1225 to read as follows:

§ 522.1225 Ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of ketoprofen.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer by intravenous injection 1.0 mg per pound of body weight once daily for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders 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.

§ 522.1228 [Removed]

■ 73. Remove reserved § 522.1228.

§ 522.1244 [Redesignated as § 522.1242 and Amended]

■ 74. Redesignate § 522.1244 as § 522.1242 and amend it as follows:

■ a. In paragraph (a), remove ''sterile aqueous'';

■ b. In paragraph (b), remove ''053501'' and in its place add ''054771''; and

■ c. Revise the section heading to read as follows:

§ 522.1242 Levamisole.

* * * * *

§ 522.1260 [Amended]

■ 75. In § 522.1260, in paragraph (b)(1), remove ''000009'' and in its place add ''054771''; and in paragraph (b)(3), remove ''046573'' and in its place add ''054771''.

■ 76. Revise § 522.1289 to read as follows:

§ 522.1289 Lufenuron.

(a) *Specifications.* Each milliliter of suspension contains 10 milligrams (mg) of lufenuron.

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

(c) *Conditions of use in cats*—(1) *Amount.* 10 mg per kilogram (4.5 mg per pound) of body weight every 6 months, by subcutaneous injection.

(2) *Indications for use.* For control of flea populations in cats 6 weeks of age and older.

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

§ 522.1315 [Amended]

■ 77. In paragraph (b) of § 522.1315, remove ''000069'' and in its place add ''054771''.

■ 78. In § 522.1335, revise the section heading and paragraphs (a) and (c)(3) to read as follows:

§ 522.1335 Medetomidine.

(a) *Specifications.* Each milliliter of solution contains 1.0 milligrams of medetomidine hydrochloride.

* * * * *

(c) * * *

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

■ 79. In § 522.1362, revise the section heading and paragraphs (c)(1) and (3) to read as follows:

§ 522.1362 Melarsomine powder for injection.

* * * * *

(c) * * *

(1) *Amount.* Administer only by deep intramuscular injection in the lumbar muscles (L_3–L_5).

* * * * *

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

§ 522.1372 [Amended]

■ 80. In paragraph (b) of § 522.1372, remove ''000009'' and in its place add ''054771''.

■ 81. Revise § 522.1380 to read as follows:

§ 522.1380 Methocarbamol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of methocarbamol.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* Administer by intravenous injection 20 mg per pound of body weight for moderate conditions or 25 to 100 mg per pound of body weight for severe conditions (tetanus and strychnine poisoning). The total cumulative dose should not to exceed 150 mg per pound of body weight.

(ii) *Horses.* Administer by intravenous injection 2 to 10 mg per pound of body weight for moderate conditions or 10 to 25 mg per pound of body weight for severe conditions (tetanus). Additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

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

(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.

§ 522.1410 [Amended]

■ 82. In paragraph (b) of § 522.1410, remove ''000009 and 054628'' and in its place add ''054628 and 054771''.

■ 83. In § 522.1451, in paragraph (b), remove ''000856'' and in its place add ''054771''; and revise the section heading to read as follows:

§ 522.1451 Moxidectin microspheres for injection.

* * * * *

■ 84. In § 522.1452, revise the section heading, paragraph (a), the heading of paragraph (c), and paragraph (c)(3) to read as follows:

§ 522.1452 Nalorphine.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of nalorphine hydrochloride.

* * * * *

(c) *Conditions of use in dogs*—

* * * * *

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

■ 85. In § 522.1465, in paragraph (c)(3), remove the first two sentences; and revise the section heading and paragraph (a) to read as follows:

§ 522.1465 Naltrexone.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams of naltrexone hydrochloride.

* * * * *

§ 522.1468 [Amended]

■ 86. In paragraph (b) of § 522.1468, remove ''000856'' and in its place add ''054771''.

■ 87. Revise § 522.1484 to read as follows:

§ 522.1484 Neomycin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of neomycin sulfate (equivalent to 35 mg of neomycin base).

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 5 mg per pound of body weight daily by intramuscular or intravenous injection, divided into portions administered every 6 to 8 hours for 3 to 5 days.

(2) *Indications for use.* For the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(3) *Limitations.* Not for parenteral use in food-producing animals because of prolonged residues in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 88. In § 522.1503, revise the section heading and paragraphs (a) and (c) to read as follows:

§ 522.1503 Neostigmine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) neostigmine methylsulfate.

* * * * *

(c) *Conditions of use*—(1) *Amount.* Administer to cattle and horses at a dosage level of 1 mg per (/) 100 pounds (lbs) of body weight subcutaneously. Administer to sheep at a dosage level of 1 to 1½ mg/100 lbs body weight subcutaneously. Administer to swine at a dosage level of 2 to 3 mg/100 lbs body weight intramuscularly. These doses may be repeated as indicated.

(2) *Indications for use.* For treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions.

(3) *Limitations.* Not for use in animals producing milk, since this use will result in contamination of the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 89. In § 522.1610, revise the section heading and paragraphs (a) and (c) to read as follows:

§ 522.1610 Oleate sodium.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of sodium oleate.

* * * * *

(c) *Conditions of use in horses*—(1) *Amount.* Administer by parenteral injection depending on the area of response desired. An injection of 1 milliliter (mL) will produce a response of approximately 15 square centimeters. Do not inject more than 2 mL per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 mL.

(2) *Indications for use.* It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(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.

■ 90. In § 522.1620, revise paragraph (c) to read as follows:

§ 522.1620 Orgotein for injection.

* * * * *

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer by deep intramuscular injection at a dosage level of 5 milligrams (mg) every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(ii) *Indications for use.* It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(iii) *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.

(2) *Dogs*—(i) *Amount.* Administer by subcutaneous injection 5 mg daily for 6 days, and thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(ii) *Indications for use.* It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

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

■ 91. In § 522.1660a, in paragraph (b), remove ''000069'' and add ''054771'' after ''048164''; and in paragraph (e)(1)(ii), revise the last sentence to read as follows:

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

* * * * *

(e) * * *

(1) * * *

(ii) * * * Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

* * * * *

§ 522.1662a [Amended]

■ 92. In § 522.1662a, in paragraphs (c)(2), (d)(2), and (e)(2), remove ''000069'' and in its place add ''054771''; and in paragraph (h)(2), remove ''055529 and 059130'' and in its place add ''000859 and 055529''.

§ 522.1662b [Amended]

■ 93. In paragraph (b) of § 522.1662b, remove ''000069'' and in its place add ''054771''.

■ 94. In § 522.1664, revise paragraph (d)(3) to read as follows:

§ 522.1664 Oxytetracycline and flunixin.

* * * * *

(d) * * *

(3) *Limitations.* Discontinue treatment at least 21 days prior to slaughter of cattle. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1680 [Amended]

■ 95. In paragraph (b) of § 522.1680, remove ''000856,'' and add ''054771'' after ''045628,''.

■ 96. Revise § 522.1696 to read as follows:

§ 522.1696 Penicillin G procaine injectable dosage forms.

§ 522.1696a [Amended]

■ 97. In § 522.1696a, in paragraphs (b)(1) and (3), remove ''000856'' and in its place add ''054771''; and in paragraph (d)(2)(iii), remove ''055529, 059130, and 061623'' and in its place add ''000859, 055529, and 061623''.

§ 522.1696b [Amended]

■ 98. In § 522.1696b, in paragraphs (b)(1), (d)(2)(i)(A), and (d)(2)(iii)(A),

remove ''053501'' and in its place add ''054771''.

§ 522.1696c [Amended]

■ 99. In § 522.1696c, in paragraph (b), remove ''053501'' and in its place add ''054771''; remove paragraph (c); and redesignate paragraph (d) as paragraph (c).

■ 100. In § 522.1698, revise the section heading and paragraphs (a), (b), (c)(1)(i), (c)(1)(iii), (c)(2)(i), and (c)(2)(iii) to read as follows:

§ 522.1698 Pentazocine.

(a) *Specifications.* Each milliliter of solution contains pentazocine lactate equivalent to 30 milligrams (mg) of pentazocine base.

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

(c) * * *

(1) * * *

(i) *Amount.* Administer 0.15 mg pentazocine base per pound of body weight daily by intravenous or intramuscular injection. In cases of severe pain, a second dose is recommended by intramuscular injection 10 to 15 minutes after the initial dose at the same level.

* * * * *

(iii) *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.

(2) * * *

(i) *Amount.* Administer 0.75 to 1.50 mg of pentazocine base per pound of body weight by intramuscular injection.

* * * * *

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

■ 101. Revise § 522.1704 to read as follows:

§ 522.1704 Pentobarbital.

(a) *Specifications.* Each milliliter of solution contains 64.8 milligrams (mg) of sodium pentobarbital.

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

(c) *Conditions of use*—(1) *Amount.* The drug is administered intravenously ''to effect''. For general surgical anesthesia, the usual dose is 11 to 13 mg per pound of body weight. For sedation, the usual dose is approximately 2 mg per pound of body weight. For relieving convulsive seizures caused by strychnine in dogs, the injection should be administered intravenously ''to effect''. The drug may be administered intraperitoneally. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration.

(2) *Indications for use.* The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(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.

■ 102. Revise § 522.1720 to read as follows:

§ 522.1720 Phenylbutazone.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) of phenylbutazone.

(2) Each milliliter of solution contains 200 mg of phenylbutazone.

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

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

(2) Nos. 000061, 000859, 054771, and 061623 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(3) Nos. 054628 and 058005 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by intravenous injection 10 mg per pound of body weight daily in three divided doses, not to exceed 800 mg daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(ii) *Indications for use.* It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount.* Administer by intravenous injection 1 to 2 grams (g) per 1,000 pounds of body weight daily in three divided doses, not to exceed 4 g daily. Limit intravenous administration to not more than 5 successive days.

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

(iii) *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.

■ 103. In § 522.1820, revise the section heading and paragraph (c) to read as follows:

§ 522.1820 Pituitary luteinizing hormone powder for injection.

* * * * *

(c) *Conditions of use*—(1) *Amount.* Cattle and horses: 25 milligrams; swine: 5 milligrams; sheep: 2.5 milligrams; and dogs: 1.0 milligram. Preferably given by intravenous injection, it may be administered subcutaneously. Treatment may be repeated in 1 to 4 weeks, or as indicated.

(2) *Indications for use.* As an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

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

■ 104. Revise § 522.1862 to read as follows:

§ 522.1862 Pralidoxime powder for injection.

(a) *Specifications.* Each vial contains 1 gram (g) of pralidoxime chloride powder for mixing with 20 cubic centimeters of sterile water for injection. Each milliliter of constituted solution contains 50 milligrams (mg) pralidoxime chloride.

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

(c) *Conditions of use*—(1) *Amount.* Administer as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 mg per pound of body weight, followed by administration of an additional 0.15 mg of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 g per horse. When administered to dogs and cats, it is 25 mg per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(2) *Indications for use.* It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

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

■ 105. Revise § 522.1881 to read as follows:

§ 522.1881 Prednisolone acetate.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) of prednisolone acetate.

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

(c) *Conditions of use*—(1) *Amount.* The drug is administered to horses intra-articularly at a dosage level of 50 to 100 mg. The dose may be repeated when necessary. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 mg. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 mg. The dose may be repeated when necessary after 7 days for two or three doses.

(2) *Indications for use.* The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and postoperatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.

(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.

■ 106. Revise § 522.1884 to read as follows:

§ 522.1884 Prednisolone sodium succinate.

(a) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams (mg) of prednisolone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for products containing 10, 20, and 50 mg equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (c)(1)(i), (ii), and (iii) of this section.

(c) *Conditions of use*—(1) *Amount and indications for use*—(i) *Horses.* Administer 50 to 100 mg as an initial dose by intravenous injection over a period of one-half to 1 minute, or by intramuscular injection, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.

(ii) *Dogs.* Administer by intravenous injection at a range of 2.5 to 5 mg per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) *Dogs and cats.* Administer by intramuscular injection for treatment of inflammatory, allergic, and less severe stress conditions, where immediate effect is not required, at 1 to 5 mg ranging upward to 30 to 50 mg in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required, oral therapy with prednisolone tablets may be substituted.

(2) *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.

■ 107. Revise § 522.1885 to read as follows:

§ 522.1885 Prednisolone tertiary butylacetate.

(a) *Specifications.* Each milliliter of suspension contains 20 milligrams (mg) of prednisolone tertiary butylacetate.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* Administer by intramuscular injection 100 to 300 mg or by intrasynovial injection at a dosage level of 50 to 100 mg. Retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.

(ii) *Dogs and cats:* Administer by intramuscular injection 1 mg per 5 pounds of body weight or intrasynovially at a dosage level of 10 to 20 mg.

(2) *Indications for use.* It is used as an anti-inflammatory agent 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.

■ 108. Revise § 522.1890 to read as follows:

§ 522.1890 Sterile prednisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 10 to 40 milligrams (mg) of prednisone.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Horses.* Administer 100 to 400 mg by intramuscular injection, repeating if necessary.

(ii) *Dogs and cats.* Administer 0.25 to 1.0 mg per pound of body weight by intramuscular injection for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.

(2) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.

(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.

■ 109. Revise § 522.1920 to read as follows:

§ 522.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each milliliter of solution contains prochlorperazine edisylate equivalent to 4 milligrams (mg) prochlorperazine and isopropamide iodide equivalent to 0.28 mg of isopropamide.

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

(c) *Conditions of use*—(1) *Amount.* (i) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in milliliters
Up to 4	0.25
5 to 14	0.5–1
15 to 30	2–3
30 to 45	3–4
45 to 60	4–5
Over 60	6

(ii) Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(2) *Indications for use.* For use in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

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

§ 522.1940 [Amended]

■ 110. In § 522.1940, in paragraph (a)(1), remove ''000856'' and in its place add ''054771''.

■ 111. In § 522.1962, in paragraph (b)(1), remove ''000856'' and in its place add

''054771''; and revise the section heading and paragraph (c)(1)(iii) to read as follows:

§ 522.1962 Promazine.

* * * * *

(c) * * *

(1) * * *

(iii) *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.

■ 112. Revise § 522.2002 to read as follows:

§ 522.2002 Propiopromazine.

(a) *Specifications.* Each milliliter of solution contains 5 or 10 milligrams (mg) propiopromazine hydrochloride.

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

(c) *Conditions of use in dogs and cats*—(1) *Amounts and indications for use.* Administer 0.05 to 0.5 mg per pound of body weight by intravenous or intramuscular injection for tranquilization. Administer 0.25 mg per pound of body weight by intravenous injection as a preanesthetic.

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

■ 113. In § 522.2005, in paragraph (b)(3), remove ''000856'' and in its place add ''054771''; and add paragraph (c)(3) to read as follows:

§ 522.2005 Propofol.

* * * * *

(c) * * *

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

■ 114. Revise § 522.2012 to read as follows:

§ 522.2012 Prostalene.

(a) *Specifications.* Each milliliter of solution contains 1 milligram of prostalene.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 5 micrograms per kilogram of body weight as a single subcutaneous injection.

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

(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.

■ 115. Revise § 522.2063 to read as follows:

§ 522.2063 Pyrilamine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of pyrilamine maleate.

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

(1) No. 000061 for use as in paragraph (c)(1)(i), (2), and (3) of this section.

(2) No. 061623 for use as in paragraph (c)(1)(ii), (2), and (3) of this section.

(c) *Conditions of use*—(1) *Amount*—(i) Horses, 40 to 60 mg per 100 pounds (lbs) body weight; foals, 20 mg/100 lbs body weight. Administer by intramuscular, subcutaneous, or intravenous injection. Dosage may be repeated every 6 to 12 hours whenever necessary.

(ii) Horses, 40 to 60 mg/100 lbs body weight; foals, 20 mg/100 lbs body weight. Administer by slow intravenous injection. Dosage may be repeated every 6 to 12 hours if necessary.

(2) *Indications for use.* It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(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.

■ 116. In § 522.2076, revise paragraph (c)(3) to read as follows:

§ 522.2076 Romifidine.

* * * * *

(c) * * *

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

■ 117. In § 522.2100, revise the section heading and paragraphs (a)(1), (a)(3), (b)(1), (b)(3), and (d)(2) to read as follows:

§ 522.2100 Selenium and vitamin E.

(a)(1) *Specifications.* Each milliliter of emulsion contains 5.48 milligrams (mg) sodium selenite (equivalent to 2.5 mg selenium) and 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

* * * * *

(3) *Conditions of use in horses*—(i) *Amount.* Administer 1 milliliter (mL) per (/) 100 pounds (lbs) of body weight by intravenous injection or by deep intramuscular injection in divided doses in two or more sites in the gluteal or cervical muscles. Administration may be repeated at 5 to 10 day intervals.

(ii) *Indications for use.* For the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(iii) *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.

(b)(1) *Specifications.* Each milliliter contains 2.19 mg of sodium selenite (equivalent to 1 mg of selenium), 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

* * * * *

(3) *Conditions of use in dogs*—(i) *Amount.* Administer by subcutaneous or intramuscular injection in divided doses in two or more sites at 1 mL/20 lbs of body weight with a minimum dosage of ¼ mL and a maximum dosage of 5 mL. The dose is repeated at 3-day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 mL per 40 lbs of body weight with a minimum dosage of ¼ mL which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

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

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

* * * * *

(d) * * *

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

* * * * *

§ 522.2120 [Amended]

■ 118. In paragraph (b) of § 522.2120, remove ''000009'' and in its place add ''054771''.

§ 522.2121 [Amended]

■ 119. In paragraph (b) of § 522.2121, remove ''000009'' and in its place add ''054771''.

■ 120. Revise § 522.2150 to read as follows:

§ 522.2150 Stanozolol.

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

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

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* For cats and small breeds of dogs: 25 mg. For larger dogs: 50 mg. Administer by deep intramuscular injection in the thigh at weekly intervals, for several weeks.

(ii) *Horses.* Administer 25 mg per 100 pounds of body weight by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks.

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

(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.

■ 121. Revise § 522.2220 to read as follows:

§ 522.2220 Sulfadimethoxine.

(a) *Specifications.* Each milliliter of solution contains:

(1) 100 milligrams (mg) of sulfadimethoxine sodium.

(2) 400 mg of sulfadimethoxine sodium.

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

(1) No. 054628 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) No. 054771 for use of the product described in paragraph (a)(2) as in paragraphs (d)(2), (3), and (4) of this section.

(3) Nos. 000859, 057561, and 061623 for use of the product described in paragraph (a)(2) as in paragraph (d)(4) of this section.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by subcutaneous, intramuscular, or intravenous injection at an initial dose of 25 mg per pound of body weight followed by 12.5 mg per pound of body weight every 24 hours thereafter. Continue treatment until the animal is free from symptoms for 48 hours.

(ii) *Indications for use.* For use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs.

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

(2) *Dogs and cats*—(i) *Amount.* Administer by intravenous or subcutaneous injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours.

(ii) *Indications for use.* For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by *Streptococci, Staphylococci, Escherichia, Salmonella, Klebsiella, Proteus,* or *Shigella* organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

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

(3) *Horses*—(i) *Amount.* Administer by intravenous injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of respiratory disease caused by Streptococcus equi (strangles).

(iii) *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.

(4) *Cattle*—(i) *Amount.* Administer an initial dose of 25 mg per pound of body weight by intravenous injection followed by 12.5 mg per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

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

■ 122. Revise § 522.2240 to read as follows:

§ 522.2240 Sulfaethoxypyridazine.

(a) *Specifications.* The drug is an aqueous solution of 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) *Amount.* Administer 2.5 grams per 100 pounds of body weight per day by intravenous injection for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxypyridazine in drinking water or tablets in accordance with §§ 520.2240a(e) and 520.2240b(e) of this chapter.

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

(3) *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 the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2340 [Amended]

■ 123. In paragraph (b) of § 522.2340, remove ''000069'' and in its place add ''054771''.

§ 522.2404 [Amended]

■ 124. In paragraph (b) of § 522.2404, remove ''000856'' and in its place add ''054771''.

■ 125. Revise § 522.2424 to read as follows:

§ 522.2424 Thiamylal.

(a) *Specifications.* The drug is a sterile powder. It is reconstituted with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by intravenous injection to effect. The average single dose is:

(i) *Dogs and cats:* 8 milligrams (mg) per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) *Swine:* 40 mg per 5 pounds (lbs) of body weight.

(iii) *Horses:* Light anesthesia, 1 gram per 500 lbs to 1,100 lbs of body weight; deep anethesia, 1 gram per 300 lbs of body weight (40 mg/12 lbs of body weight).

(iv) *Cattle:* Short duration, 20 mg/5 lbs of body weight; longer duration, 40 mg/7 lbs of body weight.

(2) *Indications for use.* It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(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.

■ 126. Revise § 522.2444 to read as follows:

§ 522.2444 Thiopental injectable dosage forms.

■ 127. Revise § 522.2444a to read as follows:

§ 522.2444a Thiopental powder for injection.

(a) *Specifications.* The drug contains sodium thiopental powder for constitution with sterile water for injection.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection as follows:

(i) 6 to 9 milligrams (mg) per pound of body weight for brief anesthesia (6 to 10 minutes).

(ii) 10 to 12 mg per pound of body weight for anesthesia of 15 to 25 minutes duration.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

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

■ 128. Revise § 522.2444b to read as follows:

§ 522.2444b Thiopental and pentobarbital powder for injection.

(a) *Specifications.* Each gram of powder contains 750 milligrams (mg) of sodium thiopental and 250 mg of sodium pentobarbital powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For total anesthesia, it is given at approximately 10 to 12 mg per pound of body weight over a period of 3.5 to 5 minutes. When preanesthetic medication is used, wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually ½ to ⅔ the normal amount is adequate.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

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

■ 129. Revise § 522.2470 to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains tiletamine hydrochloride equivalent to 50 milligrams (mg) of tiletamine base and zolazepam hydrochloride equivalent to 50 mg of zolazepam base.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Expressed as milligrams of the drug combination:

(i) *Healthy dogs:* An initial intramuscular dosage of 3 to 4.5 mg per pound of body weight for diagnostic purposes; 4.5 to 6 mg per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) *Healthy cats:* An initial intramuscular dosage of 4.4 to 5.4 mg per pound of body weight for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg per pound of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg per pound of body weight.

(2) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes) requiring mild to moderate analgesia.

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

■ 130. Revise § 522.2474 to read as follows:

§ 522.2474 Tolazoline.

(a) *Specifications.* Each milliliter of solution contains tolazoline hydrochloride equivalent to 100 milligrams (mg) of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer slowly by intravenous injection 4 mg per kilogram of body weight or 1.8 mg per pound (4 milliliters (mL) per 100 kilograms or 4 mL per 220 pounds).

(2) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(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.

§ 522.2477 [Amended]

■ 131. In paragraph (b)(3) of § 522.2477, remove ''000856'' and in its place add ''054771''.

§ 522.2478 [Amended]

■ 132. In paragraph (b) of § 522.2478, remove ''000856'' and in its place add ''054771''.

■ 133. Revise § 522.2582 to read as follows:

§ 522.2582 Trifluprom azine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of trifluprom azine hydrochloride.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs.* Administer by intravenous injection at a dosage of 0.5 to 1 mg per pound of body weight daily, or by intramuscular injection at a dosage of 1 to 2 mg per pound of body weight daily.

(ii) *Cats.* Administer by intramuscular injection at a dosage of 2 to 4 mg per pound of body weight daily.

(iii) *Horses.* Administer by intravenous or intramuscular injection at a dosage of 10 to 15 mg per 100 pounds of body weight daily to a maximum dose of 100 mg.

(2) *Indications for use.* For use in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(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.

■ 134. In § 522.2610, in paragraph (b), remove ''000856'' and in its place add ''054771''; remove paragraph (c); redesignate paragraph (d) as paragraph (c); add new paragraph (c)(1)(iii); and revise newly redesignated paragraph (c)(2)(iii) to read as follows:

§ 522.2610 Trimethoprim and sulfadiazine.

* * * * *

(c) * * *

(1) * * *

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

(2) * * *

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

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

■ 135. In § 522.2615, revise the section heading and paragraphs (a), (b), and (d) to read as follows:

§ 522.2615 Tripelennamine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of tripelennamine hydrochloride.

(b) *Sponsors.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

* * * * *

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

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

(2) *Horses*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *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.

(3) *Cattle*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intravenous or intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations.* Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 136. In § 522.2640, redesignate paragraphs (d) and (e) as paragraphs (c) and (d), respectively; and revise paragraphs (a), (b), and newly designated (d)(1)(iii), (d)(3)(i), and (d)(3)(iii) to read as follows:

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter of solution contains 50 or 200 milligrams of tylosin activity (as tylosin base).

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

(1) No. 000986 for use in paragraphs (d)(1), (2), and (3) of this section.

(2) No. 000010 for use as in paragraphs (d)(1) and (2) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not inject more than 10 milliliters per site. Do not administer within 21 days of slaughter. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

(3) * * *

(i) *Amount.* Administer 3 to 5 milligrams per pound of body weight by intramuscular injection at 12- to 24-hour intervals. Use 50 milligram per milliliter solution only.

* * * * *

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

■ 137. In § 522.2662, revise paragraph (d)(2)(iii) to read as follows:

§ 522.2662 Xylazine.

* * * * *

(d) * * *

(2) * * *

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

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■ 138. In § 522.2670, revise the section heading and paragraph (a) to read as follows:

§ 522.2670 Yohimbine.

(a) *Specifications.* Each milliliter of solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

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Dated: March 13, 2014.

Steven D. Vaughn,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2014–0072]

Special Local Regulations; Recurring Marine Events in the Seventh Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the FKCC Swim around Key West Special Local Regulation in the Atlantic Ocean and Gulf of Mexico, from 8:30 a.m. until 4:30 p.m. on June 14, 2014. This action is necessary to ensure the safety of race participants, participant vessels, spectators, and the general public from the hazards associated with this event. During the enforcement period, no person or vessel may enter the regulated area without permission from the Captain of the Port.

DATES: The regulations in 33 CFR 100.701 Table 1 will be enforced from 8:30 a.m. until 4:30 p.m. on June 14, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Marine Science Technician First Class Ian G. Bowes, Sector Key West Prevention Department, U.S. Coast Guard; telephone 305–292–8823, email *Ian.G.Bowes@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the FKCC Swim around Key West Special Local Regulation in the Atlantic Ocean and Gulf of Mexico in 33 CFR 100.701 on June 14, 2014. These regulations can be found in the Code of Federal Regulations at 33 CFR 100.701.

On June 14, 2014, Florida Keys Community College is hosting the FKCC Swim around Key West, a swim event that will circumnavigate the island of Key West starting and finishing at Smathers Beach. The event will be held on the waters of the Atlantic Ocean and Gulf of Mexico in Key West. Approximately 175 swimmers with assist boats and kayaks will participate in the swim.