

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

[47 FR 18589, Apr. 30, 1982]

§ 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.

(2) To 000061 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) *Conditions of use. Dogs and Cats.*

(1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

(3) *Limitations.* Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000061; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.

(2) To 025463; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

(b) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

(3) *Limitations.* All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997]

§ 524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.

(a) *Specifications.* Each gram of the drug contains 10 milligrams cephalonium, 5,000 units polymyxin B sulfate, 0.25 milligram flumethasone, 30 milligrams iodochlorhydroxyquin, and 40 milligrams piperocaine hydrochloride in a suitable and harmless ointment base.

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

(c) *Conditions of use.* The drug is recommended for dermal and otic use on dogs and cats for the treatment of the following conditions when complicated by bacteria, yeast, or fungus: Pyodermatitis, allergic dermatitis, dermatophytosis, nonspecific pruritus, and external otitis. For mild inflammations a periodic treatment of applying from once daily to twice weekly may be indicated. In severe conditions apply once or twice daily when continuous treatment may be indicated. Dosage per treatment should not exceed 300 milligrams of the ointment. For otic use treatment should not exceed a total of 12 days. For use only by or on the order of a licensed veterinarian.

§ 524.390 Chloramphenicol ophthalmic and topical dosage forms.

§ 524.390a Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol in a petrolatum base.

(b) *Sponsor.* See Nos. 000856 and 025463 in § 510.600(c) of this chapter for use as

§ 524.390b

in paragraph (c)(1)(i) of this section. See No. 017030 for use as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply as follows:

(i) Every 3 hours around the clock for 48 hours after which night instillations may be omitted.

(ii) Four to six times daily to affected eye for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac.

(2) *Indications for use.* Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) *Limitations.* Continue treatment for 48 hours (2 days) after eye appears normal. Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection may be cause of disease, especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

§ 524.390b Chloramphenicol ophthalmic solution.

(a) *Specifications.* Each milliliter contains 5 milligrams of chloramphenicol.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs and Cats.* (1) *Amount.* Apply one or two drops, 4 to 6 times a day for the first 72 hours, depending upon the severity of the condition. Intervals between applications may be increased after the first 2 days.

(2) *Indications for use.* Treatment of bacterial conjunctivitis caused by organisms susceptible to chloramphenicol. Therapy should be continued for 48 hours after the eye appears normal.

(3) *Limitations.* Therapy for cats should not exceed 7 days. As with other

21 CFR Ch. I (4-1-01 Edition)

antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use, and institute appropriate therapy. Prolonged use in cats may produce blood dyscrasias. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

§ 524.390c Chloramphenicol-prednisolone-tetracaine-squalane topical suspension.

(a) *Specification.* Each milliliter contains 4.2 milligrams of chloramphenicol, 1.7 milligrams of prednisolone, 4.2 milligrams of tetracaine, and 0.21 milliliter of squalane.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply two or three times daily or as needed for not more than 7 days. Severe infections should be supplemented by systemic therapy.

(2) *Indications for use.* Treatment of acute otitis externa and pyodermas (acute moist dermatitis, vulvar fold dermatitis, lip fold dermatitis, interdigital dermatitis, and juvenile dermatitis) in dogs and cats.

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

[57 FR 37334, Aug. 18, 1992]

§ 524.390d Chloramphenicol-prednisolone ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams of chloramphenicol and 2.5 milligrams of prednisolone acetate.