

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2095 is amended by revising paragraph (d) to read as follows:

§ 522.2095 Sarafloxacin solution for injection.

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(d) *Conditions of use.* 18-day embryonated broiler eggs and day-old broiler chickens:

(1) *Amount*—(i) 18-day embryonated broiler eggs: 0.05 milligram sarafloxacin in 0.1 milliliter dose in single in ovo injection.

(ii) Day-old broiler chickens: 0.1 milligrams sarafloxacin per 0.2 milliliter dose in single subcutaneous injection in the neck.

(2) *Indications for use.* For control of early chick mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations.* Dilute 1 milliliter with 99 milliliters of sterile water or physiologic saline for use. Use entire contents of diluted solution within 24 hours. No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with dosages in excess of that recommended may result in illegal drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. Do not use in eggs intended for human consumption. The effects of sarafloxacin on the reproductive function of treated fowl have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: February 7, 1997.
Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. 97-5452 Filed 3-5-97; 8:45 am]

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21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Topical Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of gentamicin topical spray in dogs for the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

EFFECTIVE DATE: March 6, 1997.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reese, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed ANADA 200-188, which provides for Gentaspray™ Topical Spray (each milliliter contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin, betamethasone valerate equivalent to 0.284 mg betamethasone) to be used topically for the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.

Approval of ANADA 200-188 for Med-Pharmex, Inc.'s, Gentaspray™ Topical Spray (gentamicin sulfate with betamethasone valerate) is as a generic copy of Schering Plough's NADA 132-338 Gentocin® Topical Spray (gentamicin sulfate with betamethasone valerate). The ANADA is approved as of January 29, 1997, and the regulations in 21 CFR 524.1044f(b) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 524.1044f is amended by revising paragraph (b) to read as follows:

§ 524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

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(b) *Sponsor.* See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

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Dated: February 11, 1997.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 32 and 53

[CC Docket No. 96-150; FCC 96-490]

Accounting Safeguards Under the Telecommunications Act of 1996: Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; Correction.

SUMMARY: This document contains a correction to the effective date of the Final Rules, which were published Tuesday, January 21, 1997, (62 FR 2918). The rules related to accounting safeguards that are necessary to satisfy the requirements of Sections 260 and 271 through 276 of the Communications Act of 1934, as amended by the Telecommunications Act of 1996 ("1996 Act"). Specifically, this Order prescribed the way incumbent local exchange carriers, including the Bell Operating Companies ("BOCs"), must account for transactions with affiliates involving, and allocate costs incurred in the provision of, both regulated telecommunications services and nonregulated services, including telemessaging, interLATA telecommunications, information, manufacturing, electronic publishing, alarm monitoring and payphone services, to ensure compliance with the 1996 Act.