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:

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

§ 522.2095 Sarafloxacin solution for injection.

(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.


Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

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 (gentamicin sulfate with betamethasone valerate) 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:


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

§ 524.1044f Gentamicin sulfate, betamethasone valerate-topical spray.

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


Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FRR Doc. 97-5453 Filed 3-5-97; 8:45 am]
EFFECTIVE DATE: The requirements and regulations established in this Order with regard to Part 32 of our Rules 47 CFR Part 32, shall become effective upon approval by OMB of the new information collection requirements adopted herein, but no sooner than July 20, 1997 (six months after publication in the Federal Register). We will allow carriers to implement these rules at an earlier date and encourage them to do so. The remaining new and/or modified information collections established in this Order shall become effective upon approval by OMB of the new information collection requirements adopted herein, but no sooner than February 20, 1997. The Commission will publish a document at a later date establishing the effective dates of these rules.

FOR FURTHER INFORMATION CONTACT: Mark Ehrlich, Attorney/Advisor, Accounting and Audits Division, Common Carrier Bureau, (202) 418-0385.

SUPPLEMENTARY INFORMATION:

Background

The Accounting Safeguards Under the Telecommunications Act of 1996 Report and Order established accounting safeguards that are necessary to satisfy the requirements of the 1996 Act, including 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.

Need for Correction

Under section 220(g) of the Act, the Commission must allow six months notice before alterations in the required manner or form of keeping accounts are to take effect.

Correction of Publication

Accordingly, the publication on January 21, 1997 is corrected as follows:

1. The effective date paragraph on page 2918, in the third column, should read: The requirements and regulations established in this Order with regard to Part 32 of our Rules, 47 CFR Part 32, shall become effective upon approval by OMB of the new information collection requirements adopted herein, but no sooner than July 20, 1997 (six months after publication in the Federal Register). We will allow carriers to implement these rules at an earlier date and encourage them to do so. The remaining new and/or modified information collections established in this Order shall become effective upon approval by OMB of the new information collection requirements adopted herein, but no sooner than February 20, 1997. The Commission will publish a document at a later date establishing the effective dates of these rules.

2. The second indented paragraph 2925, in the second column, should read:

It is further ordered that, pursuant to section 220(g) of the Communications Act of 1934, as amended, 47 U.S.C. § 220(g) and section 1.427(c) of the Commission’s Rules, 47 CFR § 1.427(c), the requirements and regulations established in this Order with regard to Part 32 of the Commission’s Rules, 47 CFR Part 32, shall be effective six months after publication in the Federal Register. The remaining requirements and regulations established in this Order shall become effective upon approval by OMB of the new information collection requirements adopted herein, but no sooner than February 20, 1997.

Federal Communications Commission
William F. Caton,
Acting Secretary.

47 CFR Part 53
[CC Docket No. 96–149; FCC 96–489]

Implementation of the Non-Accounting Safeguards of Sections 271 and 272 of the Communications Act of 1934, as Amended; Final rule; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; Correction.

SUMMARY: This documents contains corrections to the final regulations which were published Tuesday, January 21, 1997 (62 FR 2927). The regulations related to special provisions relating to Bell Operating Companies.

EFFECTIVE DATE: March 6, 1997.

FOR FURTHER INFORMATION CONTACT: Joe Di Scipio (202) 418–1580.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections affect Bell Operating Companies.

Need for Correction

As published, the final regulations contain errors which may prove to be misleading and are in need of clarification. Accordingly, the publication on January 21, 1997 of the final regulations (FCC 97–52) is corrected as follows:

1. On page 2939, in the second column, the first indented paragraph is replaced by the following:

We note that, under Computer II and Computer III, we have treated three categories of protocol processing services as basic services, rather than enhanced services. These categories include protocol processing: (1) involving communications between an end user and the network itself (e.g., for initiation, routing, and termination of calls) rather than between or among users; (2) in connection with the introduction of a new basic network technology (which requires protocol conversion to maintain compatibility with existing CPE); and (3) involving internetworking (conversions taking place solely within the carrier’s network to facilitate provision of a basic network service that result in no net conversion to the end user). We agree with PacTel that analogous treatment should be extended to these categories of protocol processing services under the statutory regime. Because the listed protocol processing services are information service capabilities used “for the management, control, or operation of a telecommunications system or the management of a telecommunications service,” they are excepted from the statutory definition of information service. These excepted protocol conversion services constitute telecommunications services, rather than information services, under the 1996 Act.

2. On page 2940, column 3, the first indented paragraph is replaced by the following:

Remote Databases/Network Efficiency. BOCs may not provide interLATA services in their own regions, either over their own facilities or through resale, before receiving authorization from the Commission under section 271(d). Therefore, we conclude that BOCs may not provide interLATA information services, except for those designated as incidental interLATA services under section 271(g), in any of their in-region states prior to obtaining section 271 authorization. Section 271(g)(4) designates as an incidental interLATA service the interLATA provision by a BOC or its affiliate of ‘‘a service that permits a customer that is located in one