

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 529

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Certifier	L. Clawson
	DDM

New Animal Drugs; Change of Sponsor's Drug Labeler Code

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 drug labeler code for Med-Pharmex, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Charles Eastin, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9077, e-mail: charles.eastin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not reflect the correct drug labeler code for Med-Pharmex, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600, 520.1044a, 520.1195, 520.1484, 520.1485, 520.2220a, 520.2345d, 522.900, 524.1044b, 524.1044f, 524.1044g, 524.1193, 524.1443, 524.1580b, 524.1580e, 524.1600a, 524.2481, and 529.1044b to correct this error. In addition, 21 CFR 524.1044b, 524.1044f, 524.1443, and 524.2481 are being revised to reflect a current format.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

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 parts 510, 520, 522, 524, and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Revise § 510.600 in the table in paragraph (c)(1) in the entry for “Med-Pharmex, Inc.” by removing “051259” and by adding in its place “054925”; and in the table in paragraph (c)(2) by removing the entry for “051259” and by numerically adding a new entry for “054925” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(2) * * *

Drug labeler code	Firm name and address
054925	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Po- mona, CA 91767-1861

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1044a [Amended]

- 4. In paragraph (b) of § 520.1044a, remove “051259” and add in its place “054925”.

§ 520.1195 [Amended]

- 5. In paragraph (b)(2) of § 520.1195, remove “051259” and add in its place “054925”.

§ 520.1484 [Amended]

- 6. In paragraph (b)(1) of § 520.1484, remove “051259” and add in its place “054925”.

§ 520.1485 [Amended]

- 7. In paragraph (b) of § 520.1485, remove “051259” and add in its place “054925”.

§ 520.2220a [Amended]

- 8. In paragraphs (a)(1) and (a)(2) of § 520.2220a, remove “051259” and add in its place “054925”.

§ 520.2345d [Amended]

- 9. In paragraphs (b)(5), (d)(1)(iii), and (d)(2)(iii) of § 520.2345d, remove “051259” and add in its place “054925”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 10. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.900 [Amended]

- 11. In paragraph (b)(1) of § 522.900, remove “051259” and add in its place “054925”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

- 13. Revise § 524.1044b to read as follows:

§ 524.1044b Gentamicin sulfate, betamethasone valerate otic solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amounts and indications for use—(i)* For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

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

- 14. Revise § 524.1044f to read as follows:

§ 524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

(a) *Specifications.* Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use.* For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

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

§ 524.1044g [Amended]

■ 15. In paragraph (b)(2) of § 524.1044g, remove “051259” and add in its place “054925”.

§ 524.1193 [Amended]

■ 16. In paragraph (b)(2) of § 524.1193, remove “051259, 051311” and add in its place “051311, 054925”.

■ 17. Revise § 524.1443 to read as follows:

§ 524.1443 Miconazole.

(a) *Specifications*—(1) Each gram of cream contains miconazole nitrate equivalent to 20 milligrams miconazole base.

(2) Each gram of lotion or spray contains miconazole nitrate equivalent to 1 percent miconazole base.

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

(1) No. 000061 for use of cream, lotion, and spray;

(2) Nos. 054925 and 058829 for use of lotion and spray.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(2) *Indications for use*. For topical treatment of infections caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

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

§ 524.1580b [Amended]

■ 18. In paragraph (b)(1) of § 524.1580b, remove “051259” and add in its place “054925”.

§ 524.1580e [Amended]

■ 19. In paragraph (b) of § 524.1580e, remove “051259” and add in its place “054925”.

§ 524.1600a [Amended]

■ 20. In paragraph (b) of § 524.1600a, remove both occurrences of “051259, and 053501” and add in their places “053501, and 054925”.

■ 21. Revise § 524.2481 to read as follows:

§ 524.2481 Triamcinolone cream.

(a) *Specifications*. The vanishing cream contains 0.1 percent triamcinolone acetate.

(b) *Sponsor*. See Nos. 053501 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Rub into affected areas two to four times daily for 4 to 10 days.

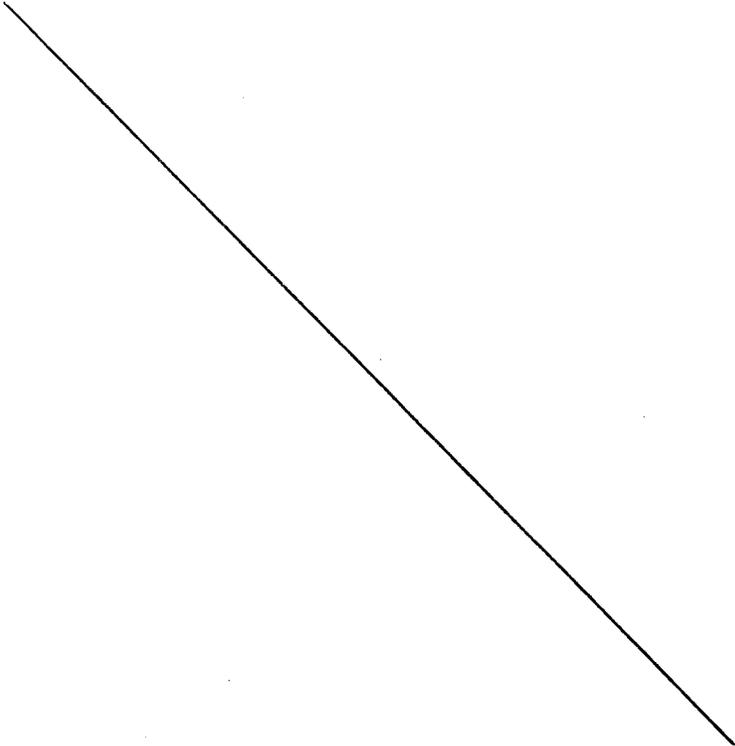
(2) *Indications for use.* As an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

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

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 22. The authority citation for 21 CFR part 529 continues to read as follows:

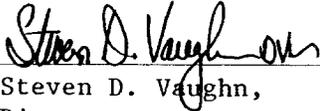
Authority: 21 U.S.C. 360b.



§ 529.1044b [Amended]

■ 23. In paragraph (b) of § 529.1044b, remove “*Sponsor*. See Nos. 000061 and 051259” and add in its place “*Sponsors*. See Nos. 000061 and 054925”.

Dated: March 7, 2006
March 7, 2006.



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