

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Certifier A. Corbin

21 CFR Parts 510, 522, and 524

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for one new animal drug application (NADA) from Chemdex, Inc., to Sparhawk Laboratories, Inc., and one NADA and two abbreviated new animal drug applications (ANADAs) from Veterinary Laboratories, Inc., to Sparhawk Laboratories, Inc.

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

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: *david.newkirk@fda.gov*.

**SUPPLEMENTARY INFORMATION:** Chemdex, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved NADA to Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215:

Application No.	21 CFR Section	Trade Name
NADA 138-255	522.1183	Iron Hydrogenated Dextran Injection

Veterinary Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, has informed FDA that it has transferred ownership of, and all rights and

interest in, the following approved NADA and two approved ANADAs to Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215:

Application No.	21 CFR Section	Trade Name
NADA 138-657	524.1580b	Nitrofurazone Ointment
ANADA 200-315	522.1260	Lincomycin Injection 25; Lincomycin Injection 100; Lincomycin Injection 300
ANADA 200-324	522.540	Dexamethasone Injection 2 milligrams/milliliters

Accordingly, the agency is amending the regulations in 21 CFR 522.540, 522.1183, 522.1260, and 524.1580b to reflect the transfer of ownership.

Following these changes of sponsorship, Chemdex, Inc., and Veterinary Laboratories, Inc., are no longer the sponsor of an approved application. Accordingly, the agency is amending 21 CFR 510.600(c) to remove the entries for Chemdex, Inc., and Veterinary Laboratories, Inc.

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 522 and 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 parts 510, 522, and 524 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. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for “Chemdex, Inc.” and “Veterinary Laboratories, Inc.” and by alphabetically adding an entry for “Sparhawk Laboratories, Inc.”; and in the table in paragraph (c)(2) by removing the entries for “017287” and “000857” and by numerically adding an entry for “058005” to read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	058005

(2) \* \* \*

Firm name and address	Drug labeler code
058005	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215

*per K. Thornton,  
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**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 522.540 [Amended]**

■ 4. Section 522.540 is amended in paragraph (a)(2)(ii) by removing “000857” and by adding in its place “058005”.

**§ 522.1183 [Amended]**

■ 5. Section 522.1183 is amended in paragraph (e)(1) by removing “017287” and by adding in its place “058005”.

**§ 522.1260 [Amended]**

■ 6. Section 522.1260 is amended in paragraph (b)(2) by removing “000857” and by adding in its place “058005”.

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

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

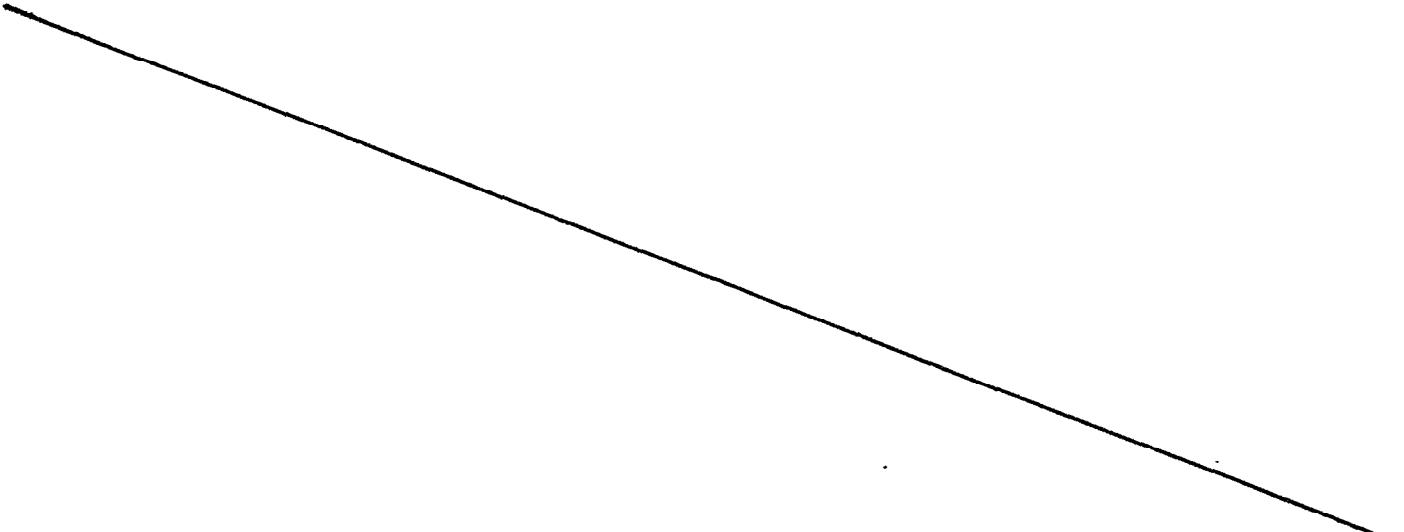
Authority: 21 U.S.C. 360b.

■ 8. Section 524.1580b is amended by revising paragraph (b) to read as follows:

**§ 524.1580b Nitrofurazone ointment.**

\* \* \* \* \*

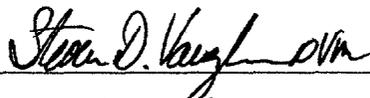
(b) *Sponsor.* For use on dogs, cats, or horses, see Nos. 000010, 000069, 023851, 050749, 051259, 058005, and 061623 in § 510.600(c) of this chapter. For use on dogs and horses, see No. 017135 in § 510.600(c) of this chapter. For use on horses, see No. 017153 in § 510.600(c) of this chapter.



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Dated: June 23, 2004

June 23, 2004.



Steven D. Vaughn,  
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Center for Veterinary Medicine.

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