DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 August 5, 2004.

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) * * *

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

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.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–17878 Filed 8–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur

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 two supplemental new animal drug applications (NADAs) filed by Pharmacia & Upjohn Co. The supplemental NADAs provide for establishing a 4-day preslaughter withdrawal period in swine injected with either a solution made from ceftiofur sodium powder or with a ceftiofur hydrochloride suspension.

DATES: This rule is effective August 5, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplements to NADA 140–338 for NAXCEL (ceftiofur sodium) Sterile Powder for Injection and to NADA 140–890 for EXCENEL RTU (ceftiofur hydrochloride) Sterile Suspension. The supplemental NADAs provide for establishing a 4-day preslaughter withdrawal period in swine injected with either product. The supplemental applications are approved as of June 18, 2004, and the regulations are amended in 21 CFR 522.313 and 522.314 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required for either.

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 in 21 CFR Part 522

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 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: 21 U.S.C. 360b.

§ 522.313 [Amended]

■ 2. Section 522.313 is amended in paragraph (d)(2)(iii) by adding ''Treated swine must not be slaughtered for 4 days following the last treatment.'' as the last sentence.

§ 522.314 [Amended]

■ 3. Section 522.314 is amended in paragraph (d)(1)(iii) by adding ''Treated swine must not be slaughtered for 4 days following the last treatment.'' as the last sentence.

Dated: July 21, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–17890 Filed 8–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Romifidine

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 a new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of romifidine hydrochloride injectable solution in horses as a sedative and analgesic, and as a preanesthetic agent.

DATES: This rule is effective August 5, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed NADA 141–229 that provides for the veterinary prescription use of SEDIVET (romifidine hydrochloride) 1% Injection as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses. SEDIVET 1% Injection is also indicated as a preanesthetic to the induction of general anesthesia in adult horses. The NADA is approved as of June 3, 2004, and 21 CFR part 522 is amended by adding § 522.2076 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application