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(2) **Airworthy Product:** For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) **Reporting Requirements:** For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI Civil Aviation Authority AD No. G-2004-0024, Issue Date: September 22, 2004, EASA approved on September 16, 2004, under approval number 2004-9648, for related information.

Issued in Kansas City, Missouri, on May 9, 2007.

Charles L. Smalley,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 07-2472 Filed 5-17-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

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's address for Modern Veterinary Therapeutics, LLC.

DATES: This rule is effective May 18, 2007.

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.hhs.gov.

SUPPLEMENTARY INFORMATION: Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157, has

informed FDA of a change of address to 1550 Madruga Ave., suite 329, Coral Gables, FL 33146. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

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 510

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

■ 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 510 is 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. In § 510.600, in the table in paragraph (c)(1) revise the entry for "Modern Veterinary Therapeutics, LLC"; and in the table in paragraph (c)(2) revise the entry for "015914" 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	
* * *			* *	
Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146			015914	
* * *			* *	
(2) * * *				
Drug labeler code		Firm name and address		
* *		* * *		
015914		Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146		
* *		* * *		

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-9555 Filed 5-17-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Powder

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 Superior Equine Pharmaceuticals, Inc. The ANADA provides for the veterinary prescription use of phenylbutazone powder administered to horses in feed for the relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective May 18, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062, filed ANADA 200-333 that provides for the veterinary prescription use of SUPERIORBUTE (phenylbutazone) Powder administered to horses in feed for the relief of inflammatory conditions associated with the musculoskeletal system. Superior Equine Pharmaceuticals, Inc.'s SUPERIORBUTE Powder is approved as a generic copy of IVX Animal Health, Inc.'s Phenylbutazone Tablets, USP, approved under NADA 91-818. The ANADA is approved as of April 20, 2007, and the regulations are amended in 21 CFR 520.1720e to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Superior Equine Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 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.

FDA has determined under 21 CFR 25.33 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.

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 510

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

21 CFR Part 520

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 and 520 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 alphabetically adding a new entry for "Superior Equine Pharmaceuticals, Inc." and in the table in paragraph (c)(2) by numerically adding a new entry for "027053" 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		
*	*	*	*	*	*
Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062			027053		
*	*	*	*	*	*
(2) * * *					
Drug labeler code			Firm name and address		
*	*	*	*	*	*
027053			Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062.		
*	*	*	*	*	*

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.

■ 4. Revise § 520.1720e, to read as follows:

§ 520.1720e Phenylbutazone powder.

(a) *Specifications*—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 027053 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.

(2) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-9559 Filed 5-17-07; 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; Butorphanol

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 IVX Animal Health, Inc. The ANADA provides for veterinary prescription use of butorphanol tartrate injectable solution in cats for the relief of pain.

DATES: This rule is effective May 18, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200-408 that provides for veterinary prescription use of Butorphanol Tartrate Injection (2mg/mL) in cats for the relief of pain. IVX Animal Health, Inc.'s Butorphanol Tartrate Injection (2mg/mL) is approved as a generic copy of Fort Dodge Animal Health, a Div. of Wyeth's TORBUGESIC-SA (butorphanol tartrate, USP), approved under NADA 141-047. The ANADA is approved as of April 20, 2007, and the regulations are amended in 21 CFR 522.246 to reflect the approval and a current format.

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 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.

FDA has determined under 21 CFR 25.33(a)(1) 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.