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 musculosketetal 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.

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.

■ 2. Revise § 522.246 to read as follows:

§ 522.246 Butorphanol.

(a) *Specifications.* Each milliliter of solution contains butorphanol (as butorphanol tartrate) in the following amounts:

(1) 0.5 milligrams (mg);
(2) 2 mg; or
(3) 10 mg

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 000856 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section; for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section; and for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) Nos. 057926 and 059130 for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.025 mg per pound of body weight by subcutaneous injection at intervals of 6 to 12 hours, as required. If necessary, increase dose to a maximum of 0.05 mg per pound of body weight. Treatment should not normally be required for longer than 7 days.

(ii) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(2) *Cats*—(i) *Amount.* Administer 0.2 mg per pound of body weight by subcutaneous injection. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days.

(ii) *Indications for use.* For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.

(3) *Horses*—(i) *Amount.* Administer 0.05 mg per pound of body weight by intravenous injection. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.

(ii) *Indications for use.* For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations.* Do not use in horses intended for human consumption.

Dated: May 3, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–9557 Filed 5–17–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD201–3117; FRL–8313–2]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Notice of administrative change.

SUMMARY: EPA is updating the materials submitted by Maryland that are incorporated by reference (IBR) into the State implementation plan (SIP). The regulations affected by this update have been previously submitted by the Maryland Department of the Environment (MDE) and approved by EPA. This update affects the SIP materials that are available for public inspection at the National Archives and Records Administration (NARA), the Air and Radiation Docket and Information Center located at EPA Headquarters in Washington, DC, and the Regional Office.

EFFECTIVE DATE: This action is effective May 18, 2007.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, EPA Headquarters Library, Room Number 3334, EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, and the National Archives and Records Administration. If you wish to obtain materials from a docket in the EPA Headquarters Library, please call the Office of Air and Radiation (OAR) Docket/Telephone number: (202) 566–1742; or the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Harold A. Frankford, (215) 814–2108 or by e-mail at *frankford.harold@epa.gov.*

SUPPLEMENTARY INFORMATION: The SIP is a living document which the State revises as necessary to address the unique air pollution problems. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations to make them part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference Federally-approved SIPs, as a result of consultations between EPA and the Office of the Federal Register (OFR). The description of the revised SIP document, IBR procedures and ''Identification of plan'' format are discussed in further detail in the May 22, 1997 **Federal Register** document. On November 29, 2004 (69 FR 69304), EPA published a document in the **Federal Register** beginning the new IBR procedure for Maryland. On February 2, 2006 (72 FR 5607), EPA published an update to the IBR material for Maryland. In this document, EPA is doing the following:

1. Announcing the update to the IBR material as of March 15, 2007.

2. Making corrections to the following entries listed in the paragraph 52.1070(c) chart, as described below:

a. COMAR 26.11.01.04—revising the text in the ''Additional explanation/citation at 40 CFR § 52.1100'' column by adding the SIP effective date.

b. COMAR 26.11.09.01—revising the text in the ''Additional explanation/citation at 40 CFR § 52.1100'' column by correcting the COMAR citation.

c. Technical Memorandum (TM) 91–01—This entry is revised to reflect EPA's approval of revisions to this TM