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

§ 520.2260b [Amended]

n 2. Section 520.2260b is amended in paragraph (f)(1) by removing ''000010'' and by adding in its place ''059130''.

Dated: February 8, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–3178 Filed 2–17–05; 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; Trenbolone and Estradiol

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 supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective February 18, 2005.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214, filed a supplement to ANADA 200–346. The supplemental ANADA provides for the use of COMPONENT TE–200 (trenbolone acetate and estradiol), a subcutaneous implant containing 200 milligrams (mg) trenbolone acetate and 20 mg estradiol in heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE–200 is approved as a generic copy of Intervet, Inc.'s REVALOR–200, approved under NADA 140–992. The application is approved as of January 14, 2005, and the regulations are amended in 21 CFR 522.2477 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 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 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.

n Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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

n 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

n 2. Section 522.2477 is amended by revising paragraph (b)(1) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(1) No. 021641 for products and uses described in paragraph (d) of this section.

* * * * *

Dated: February 8, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–3107 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment; Technical Amendment

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 approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for a new container size, a 20-gram dropper bottle, from which gentamicin sulfate, betamethasone valerate, clotrimazole ointment may be administered for the treatment of acute and chronic canine otitis externa. The regulations are also being amended to correct the indications for use to agree with approved product labeling. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective February 18, 2005.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–287 for use of TRIPLEMAX (gentamicin sulfate, U.S.P.; betamethasone valerate, U.S.P.; and clotrimazole, U.S.P. ointment) for the treatment of acute and chronic canine otitis externa. The supplement provides for a new container size, a 20-gram dropper bottle. The supplemental ANADA is approved as of January 21, 2005, and the regulations are amended in 21 CFR 524.1044g to reflect the approval. The basis of approval is discussed in the freedom of information summary.

The regulations are also being amended to correct the indications for use to agree with approved product labeling. This action is being taken to improve the accuracy of the regulations.

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.

The agency 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 Subject in 21 CFR Part 524

Animal drugs.

n 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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

n 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

n 2. Section 524.1044g is amended by revising paragraphs (b)(3), (c)(1)(ii), and (c)(2) to read as follows.

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

* * * * *

(b) * * *

(3) No. 059130 for use of 10-, 20-, or 215-g bottles.

(c) * * *

(1) * * *

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

* * * * *

Dated: February 8, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–3179 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–023A]

RIN No. 1218–AC08

Updating OSHA Standards Based on National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industries, Sawmills

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to significant adverse comment, OSHA is withdrawing the direct final rule for Updating OSHA Standards Based on National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industries, Sawmills, which was published on November 24, 2004 [69 FR 68712]. In that document, OSHA stated that if it received significant adverse comment, the agency would ''publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule * * *'' OSHA published a companion proposed rule identical to the direct final rule on the same day. [69 FR 68706]. The agency will address the significant adverse comment and the other comments on the direct final and proposed rules in a new final rule. OSHA will not institute a second comment period.

DATES: The direct final rule published on November 24, 2004 [69 FR 68712] is withdrawn effective February 18, 2005.

FOR FURTHER INFORMATION CONTACT: Lee Smith, Director, Office of Safety Systems, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2255.

Authority and Signature: This document was prepared under the direction of Jonathan L. Snare, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (*29 U.S.C. 653, 655, 657*) Secretary of Labor's Order 5–2002 (67 FR 65008), and 29 CFR part 1911.

Signed at Washington, DC, this 14th day of February 2005.

Jonathan L. Snare,

Acting Assistant Secretary of Labor.

[FR Doc. 05–3171 Filed 2–17–05; 8:45 am]

BILLING CODE 4510–26–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC–200429; FRL–7868–7]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of administrative change.

SUMMARY: EPA is publishing this action to provide the public with notice of the update to the North Carolina State Implementation Plan (SIP) compilation, which appears at 40 CFR 52.1770 (Subpart II). In particular, materials submitted by North Carolina that are incorporated by reference (IBR) into the North Carolina SIP are being updated to reflect EPA-approved revisions to North Carolina's SIP that have occurred since the last update. In this action EPA is also notifying the public of the correction of certain typographical errors in Table I of 40 CFR 52.1770(c).

DATES: This rule is effective February 18, 2005.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, GA 30303; the EPA, Air and Radiation Docket and Information Center, Air Docket (Mail Code 6102T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and the National Archives and Records Administration. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/*