revised labeling for the veterinary prescription use of injectable boldenone solution in horses.

DATES: This rule is effective November 25, 2005.

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: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, A Division of Wyeth Holdings Corp., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 34–705 that provides for veterinary prescription use of EQUIPOISE (boldenone undecylenate) by injection in horses. The supplemental NADA provides for a revised indication and food safety warning on labeling. The supplemental NADA is approved as of October 7, 2005, and the regulations are amended in 21 CFR 522.204 to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data. Therefore, a freedom of information summary is not required.

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 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

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

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

■ 2. Section 522.204 is revised to read as follows:

§ 522.204 Boldenone.

(a) *Specifications*. Each milliliter of solution contains 25 or 50 milligrams (mg) boldenone undecylenate.

(b) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.5 mg per pound body weight by intramuscular injection. Treatment may be repeated at 3-week intervals.

(2) *Indications for use*. As an aid for treating debilitated horses when an improvement in weight, hair coat, or general physical condition is desired.

(3) *Limitations*. Do not administer to horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: November 15, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–23295 Filed 11–23–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Flunixin

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 new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the veterinary prescription use of flunixin meglumine solution by intramuscular injection for the control of pyrexia associated with swine respiratory disease.

DATES: This rule is effective November 25, 2005.

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: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 101–479 that provides for the veterinary prescription use of BANAMINE-S (flunixin meglumine) Injectable Solution by intramuscular injection for the control of pyrexia associated with swine respiratory disease. The supplemental NADA is approved as of November 1, 2005, and the regulations are amended in 21 CFR 522.970 and 556.286 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning November 1, 2005.

FDA has determined under § 25.33(d)(5) 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 522 and 556 are 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. Section 522.970 is amended by adding paragraph (e)(3) to read as follows:

§ 522.970 Flunixin.

* * * * *

(e) * * *

(3) *Swine*—(i) *Amount.* Administer 2.2 mg/kg (1.0 mg/lb) of body weight as a single intramuscular injection.

(ii) *Indications for use.* For the control of pyrexia associated with swine respiratory disease.

(iii) *Limitations.* Swine must not be slaughtered for human consumption within 12 days of last treatment.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.286 is amended by adding paragraph (b)(2) to read as follows:

§ 556.286 Flunixin.

* * * * *

(b) * * *

(2) *Swine.* The tolerance for flunixin free acid (the marker residue) is:

(i) *Liver (the target tissue).* 30 ppb.

(ii) *Muscle.* 25 ppb.

* * * * *

Dated: November 15, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–23294 Filed 11–23–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2005–IN–0007; FRL–7999–3]

Approval and Promulgation of Implementation Plan; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving Indiana's April 8, 2005, submittal which revises existing sulfur dioxide (SO_2) emission limits for sources in Dearborn County, makes minor corrections removing obsolete rule language, and updates information for sources listed in the rule. These revisions will not result in an increase in SO_2 emissions in Dearborn County because no emission limits were increased.

DATES: This rule is effective on January 24, 2006, unless EPA receives adverse written comments by December 27, 2005. If EPA receives adverse comments, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2005–IN–0007, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

Agency Web site: http://docket.epa.gov/rmepub/. Regional RME, EPA's electronic public docket and comments system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: mooney.john@epa.gov.

Fax: (312) 886–5824.

Mail: You may send written comments to: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05–OAR–2005–IN–0007. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov, or e-mail. The EPA RME Web site and the Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is published in the Proposed Rules section of this **Federal Register**.

Docket: All documents in the electronic docket are listed in the RME index at *http://docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. We recommend that you telephone Charles Hatten, Environmental Engineer, at (312) 886–6031 before visiting the Region 5 office. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. General Information

A. Does This Action Apply to Me?

This action only applies to specific SO_2 sources located in Dearborn County, Indiana.