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.

■ 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 522.2478 is amended by revising paragraphs (d)(1)(i)(C), (d)(1)(ii)(C), and (d)(2)(iii) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) * * *

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Not for subsequent breeding dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 10, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–25878 Filed 11–19–04; 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; 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 new animal drug application (NADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADA provides for the addition of statements to labeling of subcutaneous implants containing estradiol warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 22, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 118–123 for ENCORE (estradiol) and COMPUDOSE (estradiol). The supplemental NADA provides for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental application is approved as of October 28, 2004, and the regulations are amended in 21 CFR 522.840 to reflect the approval and a current format. 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.

■ 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. Section 522.840 is revised to read as follows:

§ 522.840 Estradiol.

(a) *Specifications.* Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with not less than 0.5 mg oxytetracycline powder.

(b) *Sponsor.* See No. 021641 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.240 of this chapter.

(d) *Conditions of use.* For implantation in steers and heifers as follows:

(1) *Amount.* Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.

(2) *Indications for use.* For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.

(3) *Limitations.* For subcutaneous ear implantation in steers and heifers only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 10, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–25877 Filed 11–19–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OR–04–002; FRL–7835–2]

Approval and Promulgation of State Implementation Plans: Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA approves numerous revisions to the Oregon State Implementation Plan (SIP) in the State of Oregon Administrative Rules (OAR) relating to the inspection and maintenance (I/M) of motor vehicles. These revisions were submitted to EPA by the Director of the Oregon Department of Environmental Quality (ODEQ) on November 5, 1999, September 15, 2000, November 27, 2000, January 10, 2003, and April 22, 2004.

The revisions were submitted in accordance with the requirements of section 110 of the Clean Air Act (hereinafter CAA or Act).

EPA is also approving the re-numbering of the Motor Vehicle section of the Oregon Administrative Rules. Two non-SIP related rules are also removed from the SIP in this action.

DATES: This direct final rule will be effective on January 21, 2005, without further notice, unless EPA receives comment by December 22, 2004. If comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. OR–04–002, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- E-mail: *R10aircom@epa.gov.*
- Fax: (206)–553–0110.
- Mail: Office of Air, Waste, and Toxics, Environmental Protection Agency, Mail code: OAWT–107, 1200 Sixth Ave., Seattle, Washington 98101.
- Hand Delivery: Environmental Protection Agency, Office of Air, Waste, and Toxics, OAWT–107, 9th Floor, 1200 Sixth Ave., Seattle, Washington 98101. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OR–04–002. 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 regulations.gov, or e-mail. The federal regulations.gov Web site is an ''anonymous access'' system, 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 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 A. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: Publicly available docket materials are available in hard copy at the Office of Air, Waste, and Toxics, EPA Region 10, Mail code: OAQ–107, 1200 Sixth Ave., Seattle, Washington 98101; open from 8 a.m.—4:30 p.m. Monday through Friday, excluding legal holidays. The telephone number is (206) 553–1463.

FOR FURTHER INFORMATION CONTACT: Wayne Elson, Office of Air, Waste and Toxics, EPA Region 10, Mail code: OAWT–107, 1200 Sixth Avenue, Seattle WA 98101, telephone number: (206) 553–1463, or e-mail address: *elson.wayne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

The information in this section is organized as follows:

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at