and control of disease in swine. The supplemental NADA is approved as of December 22, 1999, and 21 CFR 520.445b(d)(1)(i)(A)(2) is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of data and information submitted to support approval of this application may be seen in the Dockets Management Branch (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 congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(1)(i)(A)(*2*) by removing the phrase ''; do not slaughter animals for food within 5 days of treatment''.

Dated: January 28, 2000.

Claire M. Lathers,

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

[FR Doc. 00–4731 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate 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 new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for use of a higher dose ear implant containing trenbolone acetate and estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 140–992 that provides for use of Revalor®-200, an ear implant containing 200 milligrams (mg) of trenbolone acetate and 20 mg of estradiol in 10 pellets. The implant is used for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of November 29, 1999, and the regulations are amended in 21 CFR 522.2477 by revising paragraph (b), the heading in paragraph (d)(1), and by adding paragraph (d)(1)(i)(C) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on November 29, 1999, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the ear implant containing 200 mg trenbolone acetate and 20 mg estradiol for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

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. Section 522.2477 is amended by revising paragraph (b), by removing in paragraph (d)(1) the heading ''Feedlot steers'' and by adding in its place ''Steers fed in confinement for slaughter'', and by adding paragraph (d)(1)(i)(C) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) *Sponsors.* See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), and (d)(1)(iii) of this section.

* * * * *

(d) * * *
(1) * * *
(i) * * *
(C) 200 milligrams of trenbolone acetate and 20 milligrams of estradiol (one implant consisting of 10 pellets, each pellet containing 20 milligrams of trenbolone acetate and 2 milligrams of estradiol) per implant dose.
* * * * *

Dated: January 28, 2000.

Claire M. Lathers,

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

[FR Doc. 00–4667 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 501

Reporting and Procedures Regulations: Mandatory License Application Form for Unblocking Funds Transfers

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: The Office of Foreign Assets Control (''OFAC'') is amending the Reporting and Procedures Regulations to require that license applicants seeking to unblock funds transfers under the various economic sanctions programs administered by OFAC submit their application in a standardized format.

EFFECTIVE DATE: February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Dennis P. Wood, Chief, Compliance Programs Division (tel.: 202/622–2490); or William B. Hoffman, Chief Counsel (tel.: 202/622–2410), Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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Background

The Office of Foreign Assets Control (''OFAC'') is amending the Reporting and Procedures Regulations, 31 CFR part 501 (the ''Regulations''), to require that license applications to unblock funds transfers be submitted in a standardized format. Section 501.801 of the Regulations provides procedures for requesting specific licenses, including application procedures under those statements of licensing policy contained in subpart E of the individual parts in chapter V, which note the availability of specific licenses for particular categories of transactions but do not establish requirements for the submission of specific information.

Assets blocked pursuant to the various economic sanctions programs administered by OFAC may be released through a specific license issued by OFAC in response to applications submitted by persons having an interest in the blocked funds. OFAC has for many years required certain information to be included in each license application. Until December 1998, applicants applied for a license by sending a letter with supporting documentation to OFAC. However, this non-standardized format was not conducive to the efficient processing of applications because many applications were incomplete, difficult to interpret and at times not submitted in English as required.

Accordingly, OFAC developed a form for OFAC license applications (TD–F 90–22.54) (OMB #1505–0170) in December 1998, which provided a voluntary standardized method for all applicants seeking the release of blocked funds transfers. This form was made available in electronic format on OFAC's website and by fax from OFAC's fax-on-demand service. Its use has greatly facilitated applicants' submission and OFAC's processing of applications, and obviated the need for applicants to write lengthy letter applications. This has resulted in a reduction of the overall burden of the application process.

OFAC is amending § 501.801 of the Regulations to make this form mandatory for applicants seeking the unblocking of funds transfers, and to require that the filing include the original signed application and two duplicate submissions of the entire application package. A new feature of the mandatory form is that the actual application form will generally become the license or license denial once stamped and signed by the appropriate OFAC official.

Section 501.801 of the Regulations is also being amended to require that all applications must be filed by mail or courier. Applications will no longer be accepted by fax or electronically, unless otherwise authorized. However, the application form for the unblocking of funds transfers will continue to be available on OFAC's website, where it may be completed but not signed electronically, and on OFAC's fax-on-demand service.

Since this final rule involves a foreign affairs function, Executive Order 12886 and the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

This rule is being issued without prior notice and public comment procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the collection of information contained in this rule has been submitted to and approved by the Office of Management and Budget (''OMB''), and has been assigned control number 1505–0170. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

List of Subjects in 31 CFR Part 501

Administrative practice and procedure, Banks, banking, Blocking of assets, Foreign trade, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 31 CFR part 501 is amended as set forth below:

PART 501—REPORTING AND PROCEDURES REGULATIONS

1. The authority citation for part 501 continues to read as follows:

Authority: 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1701–1706; 50 U.S.C. App. 1–44.

Subpart D—Procedures

2. Paragraph (b)(2) of § 501.801 is revised as follows: