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 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. In § 522.1260, add paragraphs (a)(4) and (b)(4) to read as follows:

§ 522.1260 Lincomycin.

(a) * * *

(4) 100 or 300 mg lincomycin.

(b) * * *

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

* * * * *

Dated: August 10, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–14509 Filed 8–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–289I]

RIN 1117–AB04

Schedules of Controlled Substances: Exempt Anabolic Steroid Products

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim rule and request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) is designating six pharmaceutical preparations as exempt anabolic steroid products under the Controlled Substances Act. This action is part of the ongoing implementation of the Anabolic Steroids Control Act of 1990.

DATES: This rule is effective September 1, 2006. Written comments must be postmarked, and electronic comments must be sent, on or before October 31, 2006.

ADDRESSES: To ensure proper handling of comments, please reference Docket No. DEA–289 on all written and electronic correspondence. Written comments sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent electronically to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided at that site. DEA will accept attachments to electronic comments in Microsoft Word, Word Perfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

The Anabolic Steroids Control Act (ASCA) of 1990 (Title XIX of Pub. L. 101–647) placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). Section 1903 of the ASCA provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the Controlled Substances Act if the products have no significant potential for abuse. The authority to exempt these products was delegated from the Attorney General to the Administrator of the Drug Enforcement Administration (28 CFR 0.100(b)), who in turn, redelegated this authority to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (28 CFR Part 0, Appendix to Subpart R, section 7(g)). The procedure for implementing this section of the ASCA is found in § 1308.33 of Title 21 of the Code of Federal Regulations. Three applications which were in conformance with 21 CFR 1308.33 were received and forwarded to the Secretary of Health and Human Services for evaluation. The purpose of this rule is to identify six products which the Deputy Assistant Administrator, Office of Diversion Control, finds meet the exempt anabolic steroid product criteria.

Anabolic Steroid Products Being Added to the List of Products Exempted From Application of the CSA

DEA received three letters dated June 8, 2005, July 1, 2005 and August 22, 2005, written to the DEA on behalf of Interpharm Inc., Lannett Company Inc., and ANDAPharm, LLC, respectively. Each of these three letters contained an application to exempt from control under the CSA two products, each containing esterified estrogens and methyltestosterone. In two letters dated November 14, 2005, DEA provided a copy of the Lannett and ANDAPharm applications to the Department of Health and Human Services (DHHS) along with a request for evaluation and a recommendation. In a letter dated November 15, 2005, DEA provided a copy of the Interpharm application to DHHS along with a request for evaluation and recommendation. In three separate letters dated March 30, 2006, the Assistant Secretary of Health for DHHS recommended that all six products, two products of esterified estrogen and methyltestosterone from each of the three applications, be exempted from control under the CSA based on their similarity to the products Estratest®, Estratest® H.S., Essian™ and Essian™ H.S., which have been exempted from control under the CSA.

DEA agrees with DHHS regarding the similarity of these products to products which have already been exempted from the regulatory controls of the Controlled Substances Act. Further, after reviewing several law enforcement databases, DEA has not found evidence of significant abuse or trafficking of these types of products.

The Deputy Assistant Administrator, having reviewed the applications, recommendations of the Secretary, and other relevant information, finds that the following six products have no significant potential for abuse: Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg); Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg); Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg); Methyltestosterone and Esterified

Estrogens (1.25 mg/0.625 mg); Esterified Estrogens/Methyltestosterone (1.25 mg/2.5 mg) Tablet; and Esterified Estrogens/Methyltestosterone (0.625 mg/1.25 mg) Tablet H.S. Information on these products is given below.

EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	Form	Ingredients	Quantity
Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg).	Interpharm, Inc	Tablets	Esterfied Estrogens Methyltestosterone	1.25 mg/Tablet. 2.5 mg/Tablet.
Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg).	Interpharm, Inc	Tablets	Esterfied Estrogens Methyltestosterone	0.625 mg/Tablet. 1.25 mg/Tablet.
Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg).	Lannett Company, Inc	Tablets	Esterfied Estrogens Methyltestosterone	1.25 mg/Tablet. 2.5 mg/Tablet.
Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg).	Lannett Company, Inc	Tablets	Esterfied Estrogens Methyltestosterone	0.625 mg/Tablet. 1.25 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (1.25 mg/2.5 mg) Tablet.	ANDAPharm, LLC	Tablets	Esterfied Estrogens Methyltestosterone	1.25 mg/Tablet. 2.5 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (0.625 mg/1.25 mg) Tablet.	ANDAPharm, LLC	Tablets	Esterfied Estrogens Methyltestosterone	0.625 mg/Tablet. 1.25 mg/Tablet.

Therefore, the Deputy Assistant Administrator hereby orders that the above anabolic steroid products be added to the list of products excluded from application of certain controls of the CSA and referenced in 21 CFR 1308.34.

Interested persons are invited to submit their comments to this interim rule. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Deputy Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

Regulatory Certifications

Regulatory Flexibility Act

The granting of exemption status relieves persons who handle the exempted products in the course of legitimate business from the registration, recordkeeping, security, and other requirements imposed by the CSA. Accordingly, the Deputy Assistant Administrator certifies that this action will not have a significant economic impact upon a substantial number of small entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

Executive Order 12866

The Deputy Assistant Administrator has determined that this is not a ''significant rule,'' as that term is used in Executive Order 12866. This rule exempts the identified steroid products from the regulatory controls that apply to controlled substances. Therefore, this rule has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This interim rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This interim rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own law. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This interim rule will not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of $117,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This interim rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including Notice of Proposed Rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest (5 U.S.C. 553(b)(3)(B). Further, the Administrative Procedure Act permits an agency to make this rule effective upon the date of publication if the rule is ''a substantive rule which grants or recognizes an exemption or relieves a restriction'' (5 U.S.C. 553(d)(1)). As the rule adds six anabolic steroid products to the list of products exempted from regulatory control under the Controlled Substances Act and provides a benefit to the affected public, DEA finds that this rule meets the criteria set forth in 5 U.S.C. 553(b)(3)(B) and 5 U.S.C. 553(d)(1) for an exception to the usual notice and comment process.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Pursuant to the authority vested in the Attorney General by section 1903 of the Anabolic Steroids Control Act of 1990, delegated to the Administrator of the Drug Enforcement Administration pursuant to 21 U.S.C. 871(a) and 28 CFR 0.100, and redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control pursuant to 28 CFR part 0, Appendix to Subpart R, section 7(g), the Deputy Assistant Administrator hereby orders that the following compounds, mixtures, or preparations containing anabolic steroids be exempted from application of sections 302 through 309 and sections 1002 through 1004 of the Controlled Substances Act (21 U.S.C. 822–829 and 21 U.S.C. 952–954) and 21 CFR 1301.13, 1301.22, 1301.71 through 1301.76 for administrative purposes only and be

included in the list of products described in 21 CFR 1308.34.

NEW EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	Form	Ingredients	Quantity
Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg).	Interpharm, Inc	Tablets	Esterfied Estrogens	1.25 mg/Tablet.
			Methyltestosterone	2.5 mg/Tablet.
Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg).	Interpharm, Inc	Tablets	Esterfied Estrogens	0.625 mg/Tablet.
			Methyltestosterone	1.25 mg/Tablet.
Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg).	Lannett Company, Inc.	Tablets	Esterfied Estrogens	1.25 mg/Tablet.
			Methyltestosterone	2.5 mg/Tablet.
Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg).	Lannett Company, Inc.	Tablets	Esterfied Estrogens	0.625 mg/Tablet.
			Methyltestosterone	1.25 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (1.25 mg/2.5 mg) Tablet.	ANDAPharm, LLC ..	Tablets	Esterfied Estrogens	1.25 mg/Tablet.
			Methyltestosterone	2.5 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (0.625 mg/1.25 mg) Tablet.	ANDAPharm, LLC ..	Tablets	Esterfied Estrogens	0.625 mg/Tablet.
			Methyltestosterone	1.25 mg/Tablet.

Dated: August 24, 2006.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E6–14516 Filed 8–31–06; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0035; FRL–8084–6]

Benthiavalicarb-Isopropyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of benthiavalicarb-isopropyl, isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate, in or on imported grape at 0.25 parts per million (ppm), tomato at 0.45 ppm, and grape, raisin at 1.0 ppm. K-I Chemical U.S.A., Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 1, 2006. Objections and requests for hearings must be received on or before October 31, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0035. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mary Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file