

on Tuesday, January 7, 1997 (62 FR 920). The regulations relate to the book-entry procedures for TVA Power Securities issued through the Federal Reserve Banks.

EFFECTIVE DATE: May 30, 1997.

FOR FURTHER INFORMATION CONTACT: Edward S. Christenbury at (423) 632-2241.

SUPPLEMENTARY INFORMATION:

Background

The regulations that are the subject of these technical amendments revised TVA's book-entry procedures to incorporate recent changes in commercial and property law and to bring them into accord with the revised book-entry procedures of the United States Department of Treasury published in the Federal Register on August 23, 1996 (61 FR 43626).

Need for Technical Amendments

As published, the regulations contain items which are in need of clarification.

List of Subjects in 18 CFR Part 1314

Accounting, Bonds, Brokers, Federal Reserve System, Reporting and recordkeeping requirements, Securities.

According, 18 CFR Part 1314 is amended by making the following technical amendments:

PART 1314—BOOK-ENTRY PROCEDURES FOR TVA POWER SECURITIES ISSUED THROUGH THE FEDERAL RESERVE BANKS

1. The authority citation for Part 1314 continues to read as follows:

Authority: 16 U.S.C. 831-831dd.

§ 1314.2 [Amended]

2. In § 1314.2, paragraph (i) is amended by revising "Book-entry Securities" to read "Book-entry TVA Power Securities" and paragraphs (g), (h), (t), and (v) are revised to read as follows:

§ 1314.2 Definition of terms.

* * * * *

(g) Other TVA Power Evidences of Indebtedness means any TVA Power Security issued consistent with section 2.5 of the TVA Basic Bond Resolution (see paragraph (r) of this section).

(h) Participant (also called "holder" in the TVA Basic Bond Resolution and in other resolutions adopted by the TVA Board of Directors relating to Book-entry TVA Power Securities) means a Person

that maintains a Participant's Security Account with a Reserve Bank.

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(t) TVA Power Bond Anticipation Obligation means any TVA Power Security issued consistent with section 2.4 of the TVA Basic Bond Resolution.

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(v) TVA Power Security means a TVA Power Bond, TVA Power Bond Anticipation Obligation, TVA Power Note, or Other TVA Power Evidence of Indebtedness issued by TVA under Section 15d of the TVA Act, as amended.

§ 1314.3 [Amended]

3. In § 1314.3, paragraph (a)(3) is amended by revising "Securities Accounts" to read "Security Accounts".

§ 1314.4 [Amended]

4. In § 1314.4, paragraph (a) introductory text is amended by removing the semicolon and adding a colon in its place, paragraph (b) is amended in the first sentence by revising "securities account" to read "Security Account"; and paragraph (d) is amended by revising "Security Documentation" to read "Securities Documentation".

Dated: May 23, 1997.

John L. Dugger,

Assistant General Counsel.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 160I]

Schedules of Controlled Substances: Exempt Anabolic Steroid Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim rule and request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) is designating ten preparations as exempt anabolic steroid products. This action, as part of the ongoing implementation of the Anabolic Steroid Control Act of 1990, removes certain regulatory controls pertaining to Schedules III substances from the designated entities.

DATES: Effective Date: May 30, 1997. Comments must be submitted on or before July 29, 1997.

ADDRESSES: Comments and objections should be submitted to the Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, 202-307-7183.

SUPPLEMENTARY INFORMATION: Section 1903 of the Anabolic Steroids Control Act of 1990 (ASCA) (title XIX of Pub. L. 101-647) provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.) if the products have no significant potential for abuse. The procedure for implementing this section of the ASCA is described in § 1308.33 of Title 21 Code of Federal Regulations. The purpose of this rule is to identify ten products for which applications were made and which the Acting Deputy Assistant Administrator finds meet the exempt anabolic steroid product criteria.

The Acting Deputy Assistant Administrator, Office of Diversion Control, having reviewed the applications, the recommendations of the Secretary of the Department of Health and Human Services, and other relevant information, finds that each of the products described below has no significant potential for abuse because of its concentration, preparation, mixture or delivery system. Therefore, pursuant to the authority vested in the Attorney General by title XIX of Public Law 101-647 as delegated to the Administrator of the DEA pursuant to 21 U.S.C. 871(a) and 28 CFR 0.100, the Acting Deputy Assistant Administrator hereby orders that the following anabolic steroid containing compounds, mixtures, or preparations be exempted from application of sections 302 through 309 and 1002 through 1004 of the CSA (21 U.S.C. 822-829 and 952-954) and §§ 1301.11, 1301.13, 1301.71 through 1301.76 of Title 21 Code of Federal Regulations for administrative purposes only and be included in the list of products described in 21 CFR 1308.34.

EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Menogen	Sage Pharmaceuticals, Shreveport, LA.	59243-570	TB	Esterified estrogens	1.25 mg.
Menogen HS	Sage Pharmaceuticals, Shreveport, LA.	59243-560	TB	Methyltestosterone	2.5 mg.
Synovex Plus, in-process, granulation.	Fort Dodge Animal Health, Fort Dodge, IA.	Drum	Esterified estrogens	0.625 mg.
Synovex Plus, in-process, bulk pellets.	Fort Dodge Animal Health, Fort Dodge, IA.	Drum	Methyltestosterone	1.25 mg.
Testoderm, 4 mg/d ...	Alza Corp., Palo Alto, CA	17314-4608	Patch	Trenbolone acetate	25 parts.
Testoderm, 6 mg/d ...	Alza Corp., Palo Alto, CA	17314-4609	Patch	Estradiol benzoate	3.5 parts.
Testoderm, with Adhesive, 6 mg/d.	Alza Corp., Palo Alto, CA	17314-2836	Patch	Trenbolone acetate	25.00 mg.
Testoderm, in-process film.	Alza Corp., Palo Alto, CA	Sheet	Estradiol benzoate	3.50 mg pellet.
Testoderm, with Adhesive, in-process film.	Alza Corp., Palo Alto, CA	Sheet	Testosterone	10 mg.
Tilapia Sex Reversal Feed (Investigational).	Rangen, Inc., Buhl, ID	Plastic Bags	Testosterone	15 mg.
				Testosterone	15 mg.
				Testosterone	15 mg.
				Testosterone	0.25 mg/cm ² .
				Testosterone	0.25 mg/cm ² .
				Methyltestosterone	60 mg/kg fish feed.

Interested persons are invited to submit their comments in writing in regard 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 Acting 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, he shall reinstate, revoke, or amend his original order as he determines appropriate.

This exemption relieves persons who handle the products in the course of legitimate business from the registration, records, reports, prescription, physical security, import, and export requirements associated with Schedule III substances. Accordingly, the Acting Deputy Assistant Administrator certifies that this action will have no impact on the ability of small businesses to compete and he therefore determines that no regulatory flexibility analysis is required.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

It has been determined that drug control matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12866. Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon review by OMB.

Nevertheless, the Acting Deputy Assistant Administrator has determined that this is not a "major rule," as that term is used in E.O. 18866, and that it would otherwise meet the applicable standards of sections 2(a) and 2(b)(2) of E.O. 12778.

Dated: May 21, 1997.

Terrance W. Woodworth,

Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 161I]

Schedules of Controlled Substances: Excluded Veterinary Anabolic Steroid Implant Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim rule and request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) is designating eight veterinary anabolic steroid implant products as being excluded from the Controlled Substances Act. This action is part of the ongoing implementation of the Anabolic Steroids Control Act.

DATES: Effective Date: May 30, 1997. Comments must be submitted on or before July 29, 1997.

ADDRESSES: Comments and objections should be submitted to the Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT:

Frank Sapienza, Chief, Drug and Chemical Evaluation Section. Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: The Anabolic Steroids Control Act of 1990 (ASCA) (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 1902(b)(41)(B)(i) of the ASCA provides for the exclusion of any anabolic steroid which the Secretary of Health and Human Services has approved for administration through implants to cattle of other nonhuman species. The procedure for implementing this section of the ASCA is described in section 1308.25 of Title 21 Code of Federal Regulations. The purpose of this rule is to identify eight products which the Acting Deputy Assistant Administrator for the Office of Diversion Control finds meet the excluded veterinary anabolic steroid implant product criteria.

The Acting Deputy Assistant Administrator, having reviewed the applications which were made in conformance with 21 CFR 1308.25, finds that the anabolic steroid products, Component™ E-H, Component™ TE-S, Component™ T-H, Component™ T-S, Revalor®-G, Revalor®-H, Synovex® H, and Synovex® Plus, are expressly intended for administration through