

• 497AD—Prospectus filed by certain investment companies under Rule 482⁶ (482 ads).⁷ Filers who are required to file 482 ads with us in accordance with Rule 497 and the NOTE to Rule 482(c) should submit their 482 ads under this new submission type.

Appendices A and B of the Filer Manual contain the descriptions and associated tagging requirements for all of the new submission types. We also have added a new section to Table 6 of Appendix A, entitled, "Miscellaneous Filings Under the Securities Act." This section groups several new and existing submission types (425, DEL AM, RW, AW, and 497AD) used by investment companies to make filings under Securities Act Rules 425, 473, 477, and 482.⁸

We have also made the following changes effective after Release 6.75 is issued:

- The EDGAR system will no longer support the following form types: SC 13E4 and SC 14D1.
- We will add the submission's accession number to the subject line of all notices to filers of acceptance or suspension.
- We will revise EDGARLink so that filers will be able to perform a version verify upgrade of the software while in a Windows environment.

Finally, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference of the Filer Manual into the Code of Federal Regulations, which incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. The revised Filer Manual and the amendments to Rule 301 will be effective on January 24, 2000.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, N.W., Washington D.C. 20549-0102. We will post electronic format copies on the SEC's Web Site. The SEC's Web Site address for the Filer Manual is <http://www.sec.gov/asec/ofis/filerman.htm>. You may also obtain copies from Disclosure Incorporated, the paper and microfiche contractor for the Commission, at (800) 638-8241.

Since the Filer Manual relates solely to agency procedures or practice,

Form N-6 for insurance company separate accounts that are registered as unit investment trust and that offer variable life policies.

⁶ 17 CFR 230.482.

⁷ The mandated electronic submissions of rule 101(a)(1)(i) of Regulation S-T [17 CFR 232.101(a)(1)(i)] omcide 482 ads where we require filers to file them with us. See Release 33-7122 at footnote 32 and accompanying text.

⁸ 17 CFR 230.425, 230.473, 230.477, and 230.482.

publication for notice and comment is not required under the Administrative Procedure Act (APA).⁹ It follows that the requirements of the Regulatory Flexibility Act¹⁰ do not apply.

The effective date for the updated Filer Manual and the rule amendments is January 24, 2000. In accordance with the APA,¹¹ we find that there is good cause to establish an effective date less than 30 days after publication of these rules.

Statutory Basis

We are adopting the amendments to Regulation S-T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,¹² Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,¹³ Section 20 of the Public Utility Holding Company Act of 1935,¹⁴ Section 319 of the Trust Indenture Act of 1939,¹⁵ and Sections 8, 30, 31, and 38 of the Investment Company Act.¹⁶

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S-T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll(d), 79t(a), 80a-8, 80a-29, 80a-30 and 80a-37.

2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The January 24, 2000 edition of the *EDGAR Filer Manual: Guide for Electronic Filing with the U.S. Securities and Exchange Commission (Release 6.75)* is incorporated into the Code of Federal

⁹ 5 U.S.C. 553(b).

¹⁰ 5 U.S.C. 601-612.

¹¹ 5 U.S.C. 553(d)(3).

¹² 15 U.S.C. 77f, 77g, 77h, 77j and 77s(a).

¹³ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w and 78ll.

¹⁴ 15 U.S.C. 79t.

¹⁵ 15 U.S.C. 77sss.

¹⁶ 15 U.S.C. 80a-8, 80a-29, 80a-30 and 80a-37.

Regulations by reference, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549-0102 or by calling Disclosure Incorporated at (800) 638-8241. Electronic format copies are available on the SEC's Web Site. The SEC's Web Site address for the Manual is <http://www.sec.gov/asec/ofis/filerman.htm>. Information on becoming an EDGAR e-mail/electronic bulletin board subscriber is available by contacting TRW/UUNET at (703) 345-8900 or at www.trw-edgar.com.

Dated: January 11, 2000.

By the Commission.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 00-1123 Filed 1-19-00; 8:45 am]

BILLING CODE 8010-10-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 187I]

RIN 1117-AA51

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 six preparations as exempt anabolic steroid products. This action, as part of the ongoing implementation of the Anabolic Steroids Control Act of 1990, removes certain regulatory controls pertaining to Schedule III substances from the designated entities.

DATES: Effective date: January 20, 2000. Comments must be submitted on or before March 20, 2000.

ADDRESSES: Comments and objections should be submitted to the 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, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

What Does This Rule Accomplish and by What Authority Is It Being Issued:

Section 1903 of the Anabolic Steroids Control Act of 1990 (title XIX of Pub. L. 101-647) (ASCA) 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 21 CFR 1308.33. The purpose of this rule is to identify six products for which applications were made and which the Deputy Assistant Administrator for the DEA Office of Diversion Control finds meet the exempt anabolic steroid product criteria.

Why Is DEA Adding Anabolic Steroid Products to the List of Exemptions?

In accordance with 21 CFR 1308.33 applications for the exemption of six anabolic steroid products were submitted by the products' manufacturers to the Deputy Assistant Administrator for the DEA Office of Diversion Control. Each application delineated a set of facts which the

applicant believed justified the exempt status of its product. The applicants provides data which they believed showed that because of the specific product preparation, concentration, mixture, or delivery system these products had no significant potential for abuse. Upon acceptance of these applications the Deputy Assistant Administrator requested from the Assistant Secretary for Health, Department of Health and Human Services (HHS) a recommendation as to whether these products which contain anabolic steroids should be considered for exemption from certain portions of the CSA. The Deputy Assistant Administrator has received the determination and recommendations of the Assistant Secretary for Health and Surgeon General, that there was sufficient evidence to establish that these products do not possess a significant potential for abuse.

Which Anabolic Steroid Products Are Affected?

The Deputy Assistant Administrator, having reviewed the applications, the recommendations of the Assistant Secretary for Health and Surgeon General, 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.

What Action Can Individuals Take if They Are Concerned About the Impact of this Rule?

Interested persons are invited to submit their comments in writing with 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 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.

Miscellaneous Matter—Correction

In a previously published rule, an exempt anabolic steroid product was identified in the list referred to in 21 CFR 1308.34 by its active ingredients rather than its trade name. See 62 FR 51776, October 3, 1997. Exemptions are granted, in accordance with the ASCA and the implementing regulations, to specific products. Therefore, DEA is correcting the list referred to in 21 CFR 1308.34 to describe the product by its specific trade name, Depo-Testadiol. The corrected information for this product in the list referred to in 21 CFR 1308.34 is:

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Depo-Testadiol	The Upjohn Company, Kalamazoo, MI.	0009-0253	Vial	Testosterone cypionate, Estradiol cypionate.	50 mg/ml, 2 mg/ml.

Why is DEA making this rule immediately effective?

This rule is being made immediately effective in order to provide a health benefit to the public by more expeditiously increasing the access to these anabolic steroid products and to reduce regulatory restrictions that DEA (in consultation with HHS) has determined to be an unnecessary burden on the businesses manufacturing these products.

Plain English

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, for the DEA Office of Diversion Control, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small business entities. The granting of exempt status relieves persons who handle the exempt products in the course of legitimate business from the registration, labeling, records, reports, prescription, physical security, and import and export restrictions imposed by the CSA.

Administrative Procedure Act 5 U.S.C. 553

This rule provides a health benefit to the public by more expeditiously increasing the access to these anabolic

steroid products and reducing regulatory restrictions that DEA and HHS have determined to be unnecessary. Therefore DEA has determined that it is contrary to the public interest to delay the effectiveness of this rule by requiring notice of proposed rulemaking and delay the effective date.

The relief from these administrative restrictions will provide monetary savings to each of the three pharmaceutical manufacturers who applied for these exemptions. In addition to the economic gain to the pharmaceutical industry, these exemptions provide significant benefits to the general public by increasing the availability of these drug products for the legitimate medical treatment for which they were intended.

Executive Order 12866

This interim rule has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Deputy Assistant Administrator, Office of Diversion Control, has determined that this rule is a significant regulatory action under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget. This regulation exempts those who handle the affected products in the course of legitimate business from the restrictions associated with Schedule III allowing for a more efficient and cost effective means of doing business. These exemptions will provide direct economic relief and financial savings to the three manufacturer applicants requesting these actions. This regulation is in the public interest and provides more expedient access to these products which, in turn, has the potential to improve the health benefits to the public.

Executive Order 13132

This rule will not have substantial direct effects on the United States, on

the relationship between the national government and the United States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This 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 the United States based companies to compete with foreign-based companies in domestic and export markets.

PART 1308—[AMENDED]

Pursuant to the authority vested in the Attorney General by section 1903 of the ASCA, delegated to the Administrator of the DEA 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 0.104, 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 1002 through 1004 of the CSA (21 U.S.C. 822–829 and 952–954) and 21 CFR 1301.11, 1301.13, 1301.71 through 1301.76 for administrative purposes only and be included in the list of products described in 21 CFR 1308.34.

§ 1308.34 Amended

EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	NDC No.	Form	Ingredients	Quality
Component E–H in Process Pellets.	Ivy Laboratories, Inc. Overland Park, KS.	Pail	Testosterone propionate, Estradiol benzoate.	25 mg/pellet, 2.5 mg/pellet.
Component E–H in Process Granulation.	Ivy Laboratories, Inc. Overland Park, KS.	Pail or Drum	Testosterone propionate, Estradiol benzoate.	10 parts, 1 part.
Component TE–S in Process Pellets.	Ivy Laboratories, Inc. Overland Park, KS.	Pail	Trenbolone acetate, Estradiol USP.	120 mg/pellet, 24 mg/pellet.
Component TE–S in Process Granulation.	Ivy Laboratories, Inc. Overland Park, KS.	Pail or Drum	Trenbolone acetate, Estradiol USP.	5 parts, 1 part.
Testoderm with Adhesive 4 mg/d.	Alza Corp, Palo Alto, CA	Export only	Patch	Testosterone	10 mg.
Testosterone Ophthalmic Solutions.	Allergan, Irvine, CA	Ophthalmic Solutions.	Testosterone	<0.6 w/v.

Dated: January 11, 2000.
John H. King,
Deputy Assistant Administrator, Office of Diversion Control.
 [FR Doc 00–1347 Filed 1–19–00; 8:45 am]
BILLING CODE 4410–09–M

ACTION: Corrections to final regulations.

SUMMARY: This document contains corrections to the final regulations which were published Tuesday, December 28, 1999 (64 FR 72756). The regulations related to postlease operations safety. These corrections relate to an incorrect citation in the preamble to the published final regulations and to three documents incorporated by reference on Boiler and Pressure Vessel Codes.

EFFECTIVE DATE: January 27, 2000.

The incorporation by reference of certain publications listed in these rules was approved by the Director of the Federal Register as of December 15, 1999, and January 27, 2000.

FOR FURTHER INFORMATION CONTACT: Kumkum Ray, (703) 787–1600.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections supersede 30 CFR 250, subpart A, General, regulations on the effective date and affect all operators and lessees on the Outer Continental Shelf.

With respect to the correction of the three documents incorporated by reference, on December 15, 1999 (64 FR 69923), MMS published a technical amendment to § 250.101, “Documents incorporated by reference,” to update versions of the ANSI/ASME Boiler and Pressure Vessel Code, Sections I, IV, and

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC32

Postlease Operations Safety

AGENCY: Minerals Management Service (MMS), Interior.