

Lock Haven, PA, William T. Piper Memorial, Takeoff Minimums and Textual DP, Amdt 1  
 Mifflintown, PA, Mifflintown, Takeoff Minimums and Textual DP, Amdt 1  
 Wise, VA, Lonesome Pine, RNAV (GPS) RWY 24, Orig  
 Wise, VA, Lonesome Pine, GPS RWY 24, Orig-A, CANCELLED  
 Green Bay, WI, Austin Straubel International, ILS OR LOC RWY 36, Amdt 8  
 Evanston, WY, Evanston-Uinta County Burns Field, RNAV (GPS) RWY 5, Amdt 2  
 Evanston, WY, Evanston-Uinta County Burns Field, RNAV (GPS) RWY 23, Amdt 2  
 Evanston, WY, Evanston-Uinta County Burns Field, VOR/DME RWY 5, Orig  
 Evanston, WY, Evanston-Uinta County Burns Field, VOR/DME RWY 23, Amdt 1

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 BILLING CODE 4910-13-P

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

[Docket No. DEA-277F]

RIN 1117-AA98

**Schedules of Controlled Substances: Exempt Anabolic Steroid Products**

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

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is finalizing an Interim Rule designating two 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:** *Effective Date:* This final rule is effective October 20, 2006.

**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). 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 (CSA) (21 U.S.C. 801 *et seq.*) 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, re delegated 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. An application which was in conformance with § 1308.33 of Title 21 of the Code of Federal Regulations was received and was forwarded to the Secretary of Health and Human Services for evaluation. The purpose of this rule is to finalize an interim rule regarding two 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 a letter dated January 12, 2004, written to the DEA on behalf of Pharmaceuticals International Inc. (PII), and an application to exempt from control under the CSA two products each containing esterified estrogens and methyltestosterone. In a letter dated April 1, 2004, DEA provided a copy of this application to the Department of Health and Human Services (DHHS) along with a request for evaluation and a recommendation. In a letter dated September 22, 2005, the Assistant Secretary of Health for DHHS recommended that both Essian™ and Essian™ H.S. be exempted from control under the CSA based on their similarity to the products, Estratest® and Estratest® H.S., respectively, both of which have been exempted from control under the CSA.

DEA agreed 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 did not find evidence of significant abuse or trafficking of these types of products. Therefore, DEA published an Interim rule with request for comments (71 FR 10835, March 3, 2006).

**Comments Received**

The DEA received no comments in response to the Interim Rule. Thus, the rule is being finalized without change. Accordingly, the Deputy Assistant Administrator hereby affirms his order that the following anabolic steroid products be added to the list of products excluded from application of certain controls of the Controlled Substances Act and referenced in 21 CFR 1308.34.

**EXEMPT ANABOLIC STEROID PRODUCTS**

Trade name	Company	Form	Ingredients	Quantity
Essian™ H.S	Pharmaceutics International Inc	Tablets	Esterified Estrogens Methyltestosterone	0.625mg/Tablet. 1.25mg/Tablet.
Essian™	Pharmaceutics International Inc.	Tablets	Esterified Estrogens Methyltestosterone	1.25mg/Tablet. 2.5mg/Tablet.

**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 final 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 final 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 final 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 final rule will not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of \$115,000,000 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 final rule is not a major rule as defined by § 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.

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

■ Pursuant to the authority vested in the Attorney General by section 1903 of the Anabolic Steroid 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 adopts as a final rule, without change, the interim rule which was published at 71 FR 10835, on March 3, 2006 amending the list described in 21 CFR 1308.34.

Dated: October 10, 2006.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control.*

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Parts 1, 35, and 54**

[TD 9294]

**RIN 1545-BD68**

**Use of Electronic Media for Providing Employee Benefit Notices and Making Employee Benefit Elections and Consents**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulation.

**SUMMARY:** This document contains final regulations setting forth standards for electronic systems that make use of an electronic medium to provide a notice to a recipient, or to make a participant election or consent, with respect to a retirement plan, an employee benefit arrangement, or an individual retirement plan. These regulations reflect the provisions of the Electronic Signatures in Global and National Commerce Act (E-SIGN). These final regulations generally affect sponsors of, and individuals entitled to benefits under, certain retirement plans, employee benefit arrangements, and individual retirement plans.

**DATES:** *Effective date:* These regulations are effective on October 20, 2006.

*Applicability date:* These regulations generally apply to applicable notices provided, and participant elections made, on or after January 1, 2007. See § 1.401(a)-21(g).

**FOR FURTHER INFORMATION CONTACT:** Pamela R. Kinard at (202) 622-6060 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Paperwork Reduction Act**

The collections of information referenced in these final regulations were previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-1632, in conjunction with the Treasury Decision (TD 8873), relating to New Technologies in Retirement Plans, published on February 8, 2000 in the **Federal Register** (65 FR 6001), and

control number 1545-1780, in conjunction with the Treasury Decision (TD 9052), relating to Notice of Significant Reduction in the Rate of Future Benefit Accrual, published on April 9, 2003 in the **Federal Register** (68 FR 17277). Responses to these collections of information are mandatory.

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 the Office of Management and Budget.

Books or records relating to these collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Background**

This document contains amendments to 26 CFR parts 1, 35, and 54 under section 401 of the Internal Revenue Code (Code) and other sections of the Code relating to retirement plans, employee benefit arrangements, and individual retirement plans. This Treasury Decision adds § 1.401(a)-21 to the Treasury regulations, which sets forth standards for the use of an electronic medium to provide applicable notices to recipients, or to make participant elections, with respect to a retirement plan, an employee benefit arrangement, or an individual retirement plan. These final regulations reflect the applicable provisions of the Electronic Signatures in Global and National Commerce Act, Public Law 106-229 (114 Stat. 464 (2000)) (E-SIGN) as it relates to the electronic delivery of notices.

The Code and regulations thereunder, and the parallel provisions of the Employee Retirement Income Security Act of 1974 (ERISA), include a number of rules that require certain notices, elections, or consents to be written or in writing. Examples of notices, elections, or consents required to be written or in writing include a section 402(f) notice (describing rollover rights), a section 411(a)(11) notice (describing a participant's benefit commencement rights), a spousal consent under section 417(a)(2), and a section 204(h) notice (notice to participants of significant reduction in rate of future benefit accrual). For a more in-depth description of retirement plan notices, elections, or consents that are required to be written or in writing, see the background section to the preamble of