

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-289F]

RIN 1117-AB04

**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 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:** *Effective Date:* This final rule is effective April 16, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Christine A. Sannerud, PhD, 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 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 (DEA) (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 21 CFR 1308.33. 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 finalize an interim rule regarding 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 (HHS) 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 HHS along with a request for evaluation and recommendation. In three separate letters dated March 30, 2006, the Assistant Secretary of Health for HHS

recommended that all six products, two products of esterified estrogen and methyltestosterone from each of 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 (71 FR 10835, March 3, 2006 and 71 FR 61876, October 20, 2006).

DEA agreed with HHS regarding the similarity of these products to products which have already been exempted from the regulatory controls of the CSA. 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 51996, September 1, 2006) exempting these products from regulatory control under the CSA.

**Comments Received**

DEA received one comment in opposition to the Interim Rule. As a basis for this objection, the commenter cited generally to Article I, Section 1 of the U.S. Constitution: "All legislative powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives." DEA has considered the comment and determined that the objection is without legal basis.

Thus, the rule is being finalized without change. Accordingly, the Deputy Assistant Administrator, Office of Diversion Control, 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
Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg).	Interpharm, Inc .....	Tablets .....	Esterified Estrogens .....	1.25 mg/Tablet.
Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg).	Interpharm, Inc .....	Tablets .....	Methyltestosterone .....	2.5 mg/Tablet.
Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg).	Lannett Company, Inc ....	Tablets .....	Esterified Estrogens .....	0.625 mg/Tablet.
Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg).	Lannett Company, Inc ....	Tablets .....	Methyltestosterone .....	1.25 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (1.25 mg/ 2.5 mg) Tablet.	ANDAPharm, LLC .....	Tablets .....	Esterified Estrogens .....	1.25 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (0.625 mg/ 1.25 mg) Tablet.	ANDAPharm, LLC .....	Tablets .....	Methyltestosterone .....	2.5 mg/Tablet.
			Esterified Estrogens .....	0.625 mg/Tablet.
			Methyltestosterone .....	1.25 mg/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. 601–612).

*Executive Order 12866*

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866. It has been determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget. This final rule exempts the identified steroid products from the regulatory controls that apply to controlled substances.

*Executive Order 12988*

This 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 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 laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

*Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) 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.

*Congressional Review Act*

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100 million 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.

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The Interim Rule with Request for Comment amending the list of exempt anabolic steroid products described in 21 CFR 1308.34 published at 71 FR 51996, September 1, 2006 is hereby adopted as a final rule without change.

Dated: March 8, 2008.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control.*

[FR Doc. E8-5173 Filed 3-14-08; 8:45 am]

**BILLING CODE 4410-09-P**

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 943**

**[SATS No. TX-058-FOR; Docket No. OSM-2007-0018]**

**Texas Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Texas proposed revisions to its regulations regarding annual permit fees. Texas intends to revise its program to improve operational efficiency.

**DATES: Effective Date:** March 17, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Alfred L. Clayborne, Director, Tulsa Field Office. Telephone: (918) 581-6430. E-mail: [aclayborne@osmre.gov](mailto:aclayborne@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Texas Program
- II. Submission of the Amendment
- III. OSM's Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision
- VI. Procedural Determinations

**I. Background on the Texas Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders

by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Texas program effective February 16, 1980. You can find background information on the Texas program, including the Secretary’s findings, the disposition of comments, and the conditions of approval, in the February 27, 1980, **Federal Register** (45 FR 12998). You can find later actions on the Texas program at 30 CFR 943.10, 943.15, and 943.16.

**II. Submission of the Amendment**

By letter dated October 2, 2007 (Administrative Record No. TX-664), Texas sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Texas sent the amendment at its own initiative.

We announced receipt of the proposed amendment in the December 17, 2007, **Federal Register** (72 FR 71293). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on January 16, 2008. We did not receive any public comments.

**III. OSM's Findings**

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

**16 Texas Administrative Code (TAC) Section 12.108 Permit Fees**

Texas proposed to revise its regulations at 16 TAC section 12.108(b)(1) through (b)(3) regarding annual permit fees by:

(1) Decreasing, from \$160.00 per acre to \$150.00 per acre, the amount of the fee in paragraph (b)(1) for each acre of land within the permit area on which coal or lignite was actually removed during the calendar year,

(2) Increasing, from \$3.00 to \$3.75, the amount of the fee in paragraph (b)(2) for each acre of land within a permit area