



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA- 601]**

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

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Order with opportunity for comment.

**SUMMARY:** The Drug Enforcement Administration is designating two pharmaceutical preparations containing esterified estrogens and methyltestosterone as exempt anabolic steroid products under the Controlled Substances Act.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Written comments must be postmarked, and electronic comments must be sent, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-601” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will

receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/Regulatory Drafting and Policy Support Section, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do

not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

### **Legal Authority**

Anabolic steroids are listed in schedule III of the Controlled Substances Act (CSA). 21 U.S.C. 802(41) and 812(c), Schedule III(e). The CSA further provides that the Attorney General may, by regulation, exempt from any or all CSA provisions any “compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.” 21 U.S.C. 811(g)(3)(C). The

authority to exempt these products has been delegated from the Attorney General to the Administrator of the Drug Enforcement Administration (DEA) (28 CFR 0.100(b)), who in turn, re-delegated this authority to the Assistant Administrator of Diversion Control (DC) (28 CFR Part 0, Appendix to Subpart R, section 7(g)). The procedures for implementing this section are found at 21 CFR 1308.33.

### **Findings of Fact**

On September 30, 2015, DEA received an application from ECI Pharmaceuticals, LLC, seeking to exempt two products combining esterified estrogens and methyltestosterone in tablets from control under the CSA. Letter from ECI Pharmaceuticals to DEA Office of Diversion Control (Sept. 30, 2015), at 1. Specifically, the products were Esterified Estrogens and Methyltestosterone 0.625/1.25mg tablets H.S. (half strength) and Esterified Estrogens and Methyltestosterone 1.25/2.5mg tablets D.S. (full strength). *Id.*

ECI based its application on the ground that DEA had previously exempted from control other tablet products combining esterified estrogens and methyltestosterone and that its products “contain the same active drug substances in the same quantities . . . and most of the same excipients as many of the” products that have been granted exemptions. *Id.* at 3. ECI’s application further stated that “[t]he deterrent effects of Esterified Estrogen when taken in combination with Methyltestosterone will not give the desired effect of one trying to abuse an anabolic steroid.” *Id.* at Attachment 1, at 2. While noting that methyltestosterone had been controlled in schedule III because of its abuse by “young and middle aged males,” ECI explained that “in combination with Esterified Estrogens, abuse of the substance would give counter effects of its intended use, causing a significant raise in the Estrogen level in males abusing the product.” *Id.*

Upon review of the application, DEA accepted it for filing. On November 2, 2015, DEA provided a copy of ECI's application to the Secretary of Health and Human Services (HHS) and requested an evaluation and a recommendation.

On September 30, 2019, the Assistant Secretary for Health (ASH) provided HHS's evaluation and recommendation to DEA. Letter from Assistant Secretary for Health, HHS, to Acting Administrator, DEA, at 1 (Sept. 30, 2019) (ASH Letter). HHS found that "[r]eports and evidence of the abuse of steroids have involved topically applied testosterone formulations and transdermal testosterone products," which are "treatment replacement therapies for deficiency of endogenous testosterone." *Id.* at Attachment (HHS Evaluation), at 3. HHS found that "[t]hese formulations contain only testosterone or testosterone esters, including methyltestosterone," but not estrogens which "generally lack anabolic effects." *Id.* HHS also found that abusers of steroids seek testosterone because of "its strong anabolic effects that lead to increased muscle mass and strength and enhance athletic endurance." *Id.* By contrast, HHS found that "bodybuilding internet forums advise users to avoid estrogen and anabolic steroid-estrogen combination products like Esterified Estrogens and Methyltestosterone H.S. and D.S. tablets because of the undesirable side effects induced by estrogen," which include "gynecomastia" and "water and fat retention under the skin." *Id.* at 3-4.

HHS further noted that ECI's two products contain the same active drug substance in the same amounts and most of the same excipients as eight different products which had previously been exempted from control. *Id.* at 4-5. HHS also performed a search of published literature databases, internet drug-user forums, and national drug reporting documents and found no "new evidence for significant abuse" of androgen/estrogen combination products. *Id.* at 6. HHS thus found that "[f]rom an abuse potential perspective, it is reasonable to conclude that the mixture

itself is undesirable,” as the mixture contains “estrogen, a hormone that lacks anabolic steroid properties sought by abusers.” *Id.* Based on “the similarity in formulation, route of administration and dosage strength” with previously exempted products, HHS concluded that there are “no meaningful differences in the abuse potential for this specific mixture of active ingredients.” *Id.*

HHS thus concluded that ECI’s “Esterified Estrogen and Methyltestosterone H.S. and D.S. tablets have no abuse potential and therefore may be exempted from CSA regulation.” *Id.* The ASH thus recommended that ECI’s “products be exempted from scheduling under the CSA.” ASH Letter, at 2. Further, after reviewing several law enforcement databases, DEA has found no evidence of significant abuse or trafficking of these types of products.

**Conclusions of Law**

Based on the evaluation and recommendation of the ASH, as well as DEA having found no evidence of significant abuse or trafficking of these types of products, the Assistant Administrator finds that “because of [their] concentration, preparation, formulation, or delivery system,” ECI’s Esterified Estrogens and Methyltestosterone 0.625/1.25mg tablets H.S. and Esterified Estrogens and Methyltestosterone 1.25/2.5mg tablets D.S., “ha[ve] no significant potential for abuse.” 21 CFR 1308.33(a). Information on these products is given below.

**Exempt Anabolic Steroid Products:**

Trade Name	Company	Form	Ingredients	Quantity
Esterified Estrogens and Methyltestosterone 1.25 mg/2.5 mg D.S.	ECI Pharmaceuticals LLC	Tablets	Esterified Estrogens Methyltestosterone	1.25 mg/Tablet 2.5 mg/Tablet
Esterified Estrogens and Methyltestosterone 0.625mg/1.25mg H.S.	ECI Pharmaceuticals LLC	Tablets	Esterified Estrogens Methyltestosterone	0.625 mg/Tablet 1.25 mg/Tablet

Therefore, the Assistant Administrator, Diversion Control Division, hereby orders that the above products containing anabolic steroids be exempted from application of sections 302, 303, 305, 307, 309, 1002, 1003, 1004 of the CSA (21 U.S.C. 822-823, 825, 827, 829, a 952-954) and 21 CFR 1301.13, 1301.22 and 1301.71 through 1301.76, and be included in the list of products described in 21 CFR 1308.34. These exemptions apply only with respect to the finished products. To the extent ECI handles methyltestosterone in the manufacturing process, because such material remains a controlled anabolic steroid, ECI must comply with all applicable registration, security and recordkeeping requirements set forth in the CSA and DEA regulations.

### **Opportunity for Comment**

Pursuant to 21 CFR 1308.33, any interested person may submit written comments on, or objections to, the exemption of either product listed in this order, within 60 days of the date of publication of this, as specified above. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Assistant Administrator, Diversion Control Division, shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments and objections filed. 21 CFR 1308.33. Thereafter, the Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate. *Id.*

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William T. McDermott,  
*Assistant Administrator.*

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