

Sundstrand) model 54H60 propellers with a blade having a serial number (S/N) below S/N 813320.

**(d) Subject**

Joint Aircraft System Component (JASC) Code 6111, Propeller Blade Section.

**(e) Unsafe Condition**

This AD was prompted by the separation of a propeller blade that resulted in the loss of an airplane and 17 fatalities. The FAA is issuing this AD to detect cracking in the propeller blade taper bore. The unsafe condition, if not addressed, could result in failure of the propeller blade, blade separation, and loss of the airplane.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Required Actions**

(1) For affected propellers identified in Planning Information, paragraph 1.E.(1), of Hamilton Sundstrand Corporation Alert Service Bulletin (ASB) 54H60-61-A154, dated August 26, 2019 ("the ASB"), perform an eddy current inspection (ECI) of all blades installed on the propeller within one year or 500 flight hours after the effective date of this AD, whichever occurs first.

(2) For affected propellers identified in Planning Information, paragraph 1.E.(2), of the ASB, perform an ECI of all blades installed on the propeller within two years or 1,000 flight hours after the effective date of this AD, whichever occurs first.

(3) Perform the ECI of the affected propeller blades using the Accomplishment Instructions, paragraph 3.C. of the ASB.

(4) If any propeller blade fails any inspection required by this AD, based on the criteria in paragraph 3.C. of the ASB, remove the blade from service and replace with a blade eligible for installation prior to the next flight.

(5) For all affected propellers, repeat the inspection required by paragraphs (g)(1) through (4) of this AD at intervals not exceeding 3 years or 1,500 flight hours, whichever comes first, after the previous inspection.

(6) Report the results of the ECI required by paragraphs (g)(1) through (5) of this AD in accordance with the Accomplishment Instructions, paragraph 3.C.(6) of the ASB.

**(h) Installation Prohibition**

After the effective date of this AD, do not install any Hamilton Sundstrand propeller blades having an S/N below 813320 on any propeller, unless the blade has first passed the inspection required by this AD. After the effective date of this AD, do not install any propeller assemblies with affected propeller blades onto any aircraft unless the affected propeller blades have passed the inspection required by paragraph (g) of this AD.

**(i) Paperwork Reduction Act Burden Statement**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a

collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

**(j) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(k) Related Information**

For more information about this AD, contact Maureen Maisttison, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7076; fax: 781-238-7199; email: [maureen.maisttison@faa.gov](mailto:maureen.maisttison@faa.gov).

**(l) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Hamilton Sundstrand Corporation (Hamilton Sundstrand) Alert Service Bulletin 54H60-61-A154, dated August 26, 2019.

(ii) [Reserved]

(3) For Hamilton Sundstrand service information identified in this AD, contact Hamilton Sundstrand, 1 Hamilton Road, Windsor Locks, CT 06096-1010, United States; phone: (877) 808-7575; email: [CRC@collins.com](mailto:CRC@collins.com).

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records

Administration (NARA). For information on the availability of this material at NARA, email: [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on June 3, 2020.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

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**BILLING CODE 4910-13-P**

## 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 June 15, 2020. Written comments must be postmarked, and electronic comments must be sent, on or before August 14, 2020.

**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](http://www.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 D.S.	1.25 mg/2.5 mg	ECI Pharmaceuticals LLC.	Tablets ...	Esterified Estrogens Methyltestosterone ...	1.25 mg/Tablet. 2.5 mg/Tablet.
Esterified Estrogens and Methyltestosterone H.S.	0.625mg/1.25mg	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.*

**William T. McDermott,**  
Assistant Administrator.

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#### BROADCASTING BOARD OF GOVERNORS

##### 22 CFR Part 531

RIN 3112–AA03

#### Firewall and Highest Standards of Professional Journalism

**AGENCY:** Broadcasting Board of Governors.

**ACTION:** Final rule.

**SUMMARY:** The Broadcasting Board of Governors is revising its regulations to clarify the practical meaning and impact of the statutory firewall contained within the United States International Broadcasting Act of 1994, as amended, upon Agency operations. Consistent with this action, this rule makes appropriate conforming changes.

**DATES:** This rule is effective as of June 11, 2020.

**FOR FURTHER INFORMATION CONTACT:** Armanda Mathews, Staff Assistant, email at: [Rule\\_Comments@usagm.gov](mailto:Rule_Comments@usagm.gov) or (202) phone 202–920–2005.

#### SUPPLEMENTARY INFORMATION:

##### Background

The United States Agency for Global Media (USAGM), identified in the International Broadcasting Act of 1994, as amended, as the Broadcasting Board of Governors (BBG), is an independent establishment of the federal government that exercises authority over non-military United States government broadcasting.<sup>1</sup> USAGM currently

operates five networks—Voice of America (VOA), the Office of Cuba Broadcasting (OCB), Radio Free Europe/Radio Liberty (RFE/RL), Radio Free Asia (RFA) and the Middle East Broadcasting Networks (MBN)—that reach a cumulative weekly worldwide audience of approximately 400 million people.

Before reaching the end of its tenure, the Governing Board of the Agency wanted to codify and memorialize definitions and practices associated with the firewall. In 2016, the Board created a firewall working group to investigate the firewall and its sources. This rule was developed by that working group and subsequently passed unanimously by the Governing Board. (This supplementary information was added by the Agency to provide additional background as to impetus for the rule). The impetus was to demystify the firewall, including by making clear what the firewall is not.

The firewall is essential to ensuring the continued credibility and therefore effectiveness of the journalism provided by USAGM funded networks. The firewall protects the editorial independence of the networks journalists. It does not prevent oversight of the journalism consistent with the highest standards of professional journalism and editorial independence; nor does it prevent VOA or any of the networks carrying out all enumerated elements of their mission, including that of VOA to “tell America’s Story”. H.R. Conf. Rep. No. 432, 104–6 Cong., 2nd Sess. 127 (1998).

#### Overview of the Rule

Pursuant to the background above, and in light of the Board’s desire to codify a common-sense definition of the firewall, consistent with the law, the

<sup>1</sup> Under Section 1288 of the NDAA, the CEO was authorized to change the name of the Agency. On August 22, 2018, the CEO exercised this power and renamed the BBG the United States Agency for Global Media. This and subsequent CEOs retain the authority to rename the Agency.