730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(j) Related Information

For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; *Kathleen.Arrigotti@faa.gov.*

(k) 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 this AD specifies otherwise.

(i) Agência Nacional de Aviação Civil (ANAC) AD 2020–04–01R01, effective May 22, 2020.

(ii) [Reserved]

(3) For ANAC AD 2020–04–01R01, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, BRAZIL, Tel: 55 (12) 3203–6600; Email: *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0584.

(5) You may view this material 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,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 1, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–27619 Filed 12–15–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–671]

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 denying applications to designate four in-process preparations containing trenbolone acetate as exempt anabolic steroid products under the Controlled Substances Act.

DATES: This order is effective December 16, 2020. Written comments must be postmarked, and electronic comments must be sent, on or before February 16, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–671'' on all electronic and written correspondence, including any attachments.

Electronic comments: The Drug Enforcement Administration (DEA) encourages 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 and are discouraged. 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. 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 made publicly available, 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 publicly available 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 made publicly available, 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 or personal identifying 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

DEA received an application from Ivy Animal Health, Inc. (Ivy), dated March 27, 2015, seeking to exempt two anabolic steroid-containing product preparations containing trenbolone acetate from control under the CSA. Letter from Ivy Animal Health, Inc. to DEA (Mar. 27, 2015), at 1. Specifically, the product preparations were Component TE–H in-process granulation and Component TE–H in-process pellets in bulk containers. *Id.*

Ivy based its application on the grounds that DEA had previously exempted other in-process granulations and pellets containing trenbolone acetate, and the Component TE–H ''product formulations contain the same active ingredients Trenbolone acetate and Estradiol'' as the other in-process materials that are currently exempt. *Id.* Ivy's application further stated that ''[t]he presence of Estradiol in the formulation with Trenbolone acetate renders the Component TE–H in process granulation and pellets unusable for anabolic steroid abuse.'' *Id.* at 4–5. Ivy noted that DEA has ''previously identified Component TE–S in process granulation and in process pellets as exempt from the CSA as the presence of Estradiol in the formulation prevented significant potential for abuse.'' *Id.* at 5.

Upon review of the application, DEA accepted it for filing. On April 29, 2015, DEA provided a copy of Ivy's application to the Secretary of Health and Human Services (HHS) and requested an evaluation and a recommendation.

DEA also received an application from Ivy Animal Health, Inc., dated April 30, 2015, seeking to exempt two anabolic steroid-containing product preparations containing trenbolone acetate from control under the CSA. Letter from Ivy Animal Health, Inc. to DEA (Apr. 30, 2015), at 1. Specifically, the product preparations were Component T–H in-process granulation and Component T–H in-process pellets in bulk containers. *Id.*

Ivy based its application on the grounds that DEA had ''previously identified Component TE–S in process granulation and in process pellets as exempt from the CSA as the formulation prevented significant potential for abuse.'' *Id.* The application noted that the ''combination of [trenbolone acetate] with the excipient materials under the manufacturing process conditions removes significant potential for abuse of the anabolic steroid in the granulation mixture and resultant in process pellets.'' *Id.* Ivy further noted that this formulation ''is identical to that of the Component® T–H packaged product pellets and presents no more potential for abuse than that of the excluded packaged implant product.'' *Id.* at 4. Ivy claimed that for Component T–H in-process granulation and Component T–H in-process pellets, ''[c]omplicated manipulation of the material, including dissolution, separation, and reconstituting, would be required to convert the in process material to Trenbolone acetate and prepare it for injection or some other delivery method.'' *Id.* at 5.

Upon review of the application, DEA accepted it for filing. On June 4, 2015, DEA provided a copy of Ivy's application to the Secretary of HHS and requested an evaluation and a recommendation.

On October 8, 2019, the Assistant Secretary for Health (ASH) provided HHS's evaluation and recommendation to DEA for both applications. Letter from Assistant Secretary for Health, HHS, to Acting Administrator, DEA, at 1 (Oct. 8, 2019) (ASH Letter). HHS found that ''[a]lthough there is no evidence that trenbolone is being obtained from in-process materials there is evidence that it is being abused.'' *Id.* HHS noted the availability of ''protocols or kits to purify trenbolone from marketed cattle pellets'' and concluded that these ''do-it-yourself kits'' makes the ''in-process materials easy to abuse.'' *Id.*

With respect to the inclusion of estradiol in Component TE–H in-process granulation and Component TE–H in-process pellets, HHS found that ''protocols and kits have been developed to purify trenbolone from estradiol.'' *Id.* Although HHS had previously ''recommended that DEA exempt in-process substances containing trenbolone and estradiol'' on the basis that ''inclusion of estradiol deterred abuse,'' because these kits and protocols are now available, ''it can no longer be concluded that the addition of estradiol to a substance containing trenbolone acetate deters the abuse of trenbolone acetate.'' *Id.*

HHS thus concluded ''that the products Component T–H in-process granulation and Component T–H in-process pellets, and Component TE–H in-process granulation and Component TE–H in-process pellets do not fit into the category of having no significant potential for abuse based on concentration, preparation, formulation, or delivery system.'' *Id.* The ASH thus recommended that Ivy's ''products be denied exemption from scheduling under the CSA.'' *Id.*

Further, after a review of the available kits and protocols, DEA finds this information credible, easy to understand, and requires no specialized skill or experience to carry out the required steps. Thus, DEA concludes that trenbolone acetate can be easily separated from estradiol and other excipient materials used to make Component TE–H in-process granulation, Component TE–H in-process pellets, Component T–H in-process granulation, and Component T–H in-process pellets. The composition of these in-process materials containing significant quantities of trenbolone acetate does not prevent significant potential for abuse.

Conclusions of Law

Based on the evaluation and recommendation of the ASH, as well as DEA's review of available evidence of diversion of these types of products, the Assistant Administrator does not find that ''because of [their] concentration, preparation, formulation, or delivery system,'' Ivy's Component TE–H in-process granulation, Component TE–H in-process pellets, Component T–H in-process granulation, and Component T–H in-process pellets ''ha[ve] no significant potential for abuse.'' 21 CFR 1308.33(a).

Therefore, the Assistant Administrator, Diversion Control Division, hereby orders that the above products containing anabolic steroids not be exempted from application of any section of the CSA, and they are not to be included in the list of products described in 21 CFR 1308.34. These in-process materials remain controlled as an anabolic steroid in schedule III. Unless specifically excepted, to the extent Ivy handles trenbolone acetate in the manufacturing process, Ivy must comply with all applicable registration, security and recordkeeping requirements set forth in the CSA and DEA regulations. Exemptions granted or denied under 21 CFR 1308.33 are

product- and manufacturer-specific, and the present order does not address any other product currently listed in 21 CFR 1308.34.

This order does not apply to the final, packaged, and labeled products ''containing an anabolic steroid, that are expressly intended for administration through implants to cattle or other nonhuman species'' where the products ''have been approved by the Secretary of Health and Human Services for such administration.'' 21 CFR 1308.26(a). Under 21 U.S.C. 802(41)(B)(i), such products are excepted from the definition of an anabolic steroid without undergoing the exemption process described in 21 CFR 1308.33, and without any evaluation or determination of their abuse potential.

Opportunity for Comment

Pursuant to 21 CFR 1308.33, any interested person may submit written comments on, or objections to, the denial of an exemption for any product listed in this order, within 60 days of the date of publication of this order, 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, may reconsider the application in light of the comments and objections filed. 21 CFR 1308.33. Thereafter, the Assistant Administrator shall amend his original order as he determines appropriate. *Id.*

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–25288 Filed 12–15–20; 8:45 am]

BILLING CODE 4410–09–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 228

[AID–2020–0004]

RIN 0412–AB02

Procurement of Certain Essential Medical Supplies To Address the COVID–19 Pandemic; Correction

AGENCY: Agency for International Development.

ACTION: Correcting amendments.

SUMMARY: On October 23, 2020, the United States Agency for International Development (USAID) issued a Temporary Final Rule (TFR) amending our regulations to allow USAID to waive ''Source and Nationality'' rules to provide for increased flexibility, targeting, and speed of procurement of Emergency Medical Supplies (EMS) required to address the COVID–19 pandemic worldwide. That TFR inadvertently resulted in the deletion of defined terms. This document corrects the TFR by restoring those definitions.

DATES: The rule is effective on December 16, 2020, through April 30, 2021, and is applicable beginning October 23, 2020.

FOR FURTHER INFORMATION CONTACT: Natalie J. Freeman (or designee), Attorney Advisor, Office of the General Counsel, USAID, 1300 Pennsylvania Ave. NW, Washington, DC 20523, *GCFEDREGMailbox@usaid.gov.*

SUPPLEMENTARY INFORMATION: This document corrects 22 CFR 228.01, which was amended by the TFR published in the **Federal Register** on October 23, 2020 (85 FR 67443). The TFR revised the definitions in § 228.01 by adding a new definition for ''Essential medical supplies.'' This new definition was intended to be added to the existing list in alphabetical order, but it inadvertently resulted in the deletion of the terms previously defined in § 228.01. After publication, stakeholders notified USAID of the missing definitions, which are used throughout 22 CFR part 228. This document effectuates the intent of the TFR by restoring the definitions in § 228.01 and adding the definition of ''Essential medical supplies'' to the alphabetical list. This correction does not otherwise affect the changes made by the TFR to 22 CFR part 228, or its effective dates of October 23, 2020, through April 30, 2021.

List of Subjects in 22 CFR Part 228

Government procurement.

For the reasons discussed above, 22 CFR part 228 is corrected by making the following correcting amendments:

PART 228—RULES FOR PROCUREMENT OF COMMODITIES AND SERVICES FINANCED BY USAID

■ 1. The authority citation for 22 CFR part 228 continues to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended, E.O. 12163, Sept. 29, 1979, 44 FR 56673: 3 CFR 1979 Comp., p. 435.

■ 2. Revise § 228.01 to read as follows:

§ 228.01 Definitions.

As used in this part, the following terms shall have the following meanings:

Advanced developing countries mean those countries that are categorized by the World Bank as upper middle income countries according to their gross national income per capita, except for those countries in which USAID provides assistance. USAID will maintain a list of advanced developing countries primarily based on the most recent World Bank determinations, and will make the list available in USAID's Automated Directives System, ADS 310. This list will include determinations made under § 228.17 of this part.

Available for purchase means for commodities, that the commodity is offered for sale in a country in the authorized principal geographic code at the time of purchase from the supplier, irrespective of the place of manufacture or production, unless it is a prohibited source country. If applicable, the commodity must also be able to be serviced, and, if warrantied, have a valid warranty. For services, available for purchase means the service is offered from a vendor which has complied with nationality and foreign government-owned organization requirements of this regulation, and is otherwise organized in a country in the authorized principal geographic code designated in an implementing instrument. This definition does not apply to procurements under the geographic Code 935, see § 228.03 of this part, because that geographic code is for any country or area except for prohibited source countries.

Commission means any payment or allowance by a supplier to any person for the contribution which that person has made to secure the sale or contract for the supplier or which that person makes to securing on a continuing basis similar sales or contracts for the supplier.

Commodities or *goods* means any material, article, supply, good, or equipment.

Commodity-related services means delivery services and/or incidental services.

Cooperating country or *recipient country* means the country receiving the USAID assistance subject to this part 228, and includes all the countries receiving assistance under a regional program or project.

Delivery means the transfer to, or for the account of, an importer of the right to possession of a commodity, or, with respect to a commodity-related service, the rendering to, or for the account of, an importer of any such service.

Delivery service means any service customarily performed in a commercial export or import transaction which is necessary to affect a physical transfer of commodities to the cooperating/recipient country. Examples of such