needed to completely close the lavatory door.

(9) The on-board wheelchair must prominently display instructions for proper use.

(f) You are not required to expand the existing FAA-certificated on-board wheelchair stowage space of the aircraft, or modify the interior arrangement of the lavatory or the aircraft, in order to comply with this section. However, if the on-board wheelchair that you obtain does not fit within the original stowage space, and another space exists (*e.g.,* an overhead compartment) where the on-board wheelchair could fit consistent with FAA safety standards, then you must stow the on-board wheelchair in that space and must request any necessary FAA approval to do so. You are not required to make the on-board wheelchair available if the pilot-in-command determines that safety or security considerations preclude its use.

(g) You must acquire an OBW that complies with as many requirements set forth in paragraph (e) of this section as are available. You are not responsible for the failure of third parties to develop and deliver an on-board wheelchair that complies with a requirement set forth in paragraph (e) of this section so long as you make reasonable efforts to purchase such an OBW and inform the Department at the address cited in § 382.159 that an on-board wheelchair meeting that requirement is unavailable despite your reasonable efforts. If you cannot provide a wheelchair meeting requirement (e)(8) of this section despite your reasonable efforts, then you must provide, on request, the use of the visual barrier (*e.g.,* a curtain) described in § 382.63(f)(7) to enable the passenger to perform lavatory functions in privacy.

(h) If you replace an on-board wheelchair on aircraft with an FAA-certificated maximum seating capacity of 125 or more after October 2, 2026, then you must replace it with an on-board wheelchair that meets the standards set forth in paragraph (e) of this section.

Issued this 25th day of July, 2023, in Washington, DC.

Peter Paul Montgomery Buttigieg,

Secretary.

[FR Doc. 2023–16178 Filed 7–31–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1300, 1302, and 1308

[Docket No. DEA–481]

RIN 1117–AB81

Implementation of the Designer Anabolic Steroid Control Act of 2014

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

ACTION: Final rule.

SUMMARY: On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014 (DASCA) became law. The Act amended the Controlled Substances Act to revise and add specified substances to the definition of ''anabolic steroid.'' The Act provided a new mechanism for temporary and permanent scheduling of anabolic steroids, and added specific labeling requirements for products containing anabolic steroids. The Drug Enforcement Administration (DEA) is publishing this rule to amend and reorganize its regulations to make them consistent with DASCA regarding the updated definition, specific substances, criteria and timeframes applicable to temporary and permanent scheduling of anabolic steroids, and labeling requirements.

DATES: This final rule is effective August 1, 2023.

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

SUPPLEMENTARY INFORMATION: On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014, Public Law 113–260 (128 Stat. 2929) (DASCA), became law. The purpose of this final rule is to codify in Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by DASCA. This final rule merely conforms the DEA's regulations to the statutory amendments to the CSA that have already taken effect, and does not add additional requirements to the regulations. Thus, because this rule does no more than incorporate statutory amendments into DEA's regulations, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary; and the rule is instead being issued as a final rule effective immediately.

DASCA's Changes to the CSA

A House Report for DASCA stated that the purpose of the Act is ''to more effectively regulate anabolic steroids.'' H.R. Rep. No. 113–587, Part 2, at 4 (2014). DASCA makes four changes to the CSA: DASCA (1) revises and adds additional substances to the existing definition of ''anabolic steroid'' in 21 U.S.C. 802(41); (2) provides a new mechanism for temporary and permanent scheduling of anabolic steroids in 21 U.S.C. 811(i); (3) adds labeling requirements for anabolic steroids under 21 U.S.C. 825(e); and (4) provides new penalties for violating the labeling requirements under 21 U.S.C. 842(a)(16) and 842(c)(1)(C) and (D).

It is evident from the enactment of DASCA that Congress believed the prior two public laws addressing steroids under the CSA (the Anabolic Steroids Control Act of 1990, Pub. L. 101–647, and the Anabolic Steroid Control Act of 2004, Pub. L. 108–358) had not sufficiently stemmed the misuse of anabolic steroids by athletes, students, and others. Among other things, Congress found that the prior statutory definition of an anabolic steroid was too narrow and that this narrowness was being exploited by some manufacturers and distributors. DASCA was designed to remedy this situation by: (1) expressly controlling under the CSA additional anabolic steroids that have emerged in the United States in recent years; and (2) expanding the definition of an anabolic steroid to allow other such steroids to be controlled as they emerged in the future. Indeed, the word ''designer'' in DASCA's title reflects that Congress was targeting those who sought to circumvent the CSA by producing anabolic steroids that were slightly different in chemical structure from those substances specifically listed in the CSA but which were intended to cause the same effects—and thus were potentially harmful to users. The following statement by one of the sponsors of the legislation, Senator Whitehouse, illustrates these considerations:

> [A] loophole in current law allows for designer anabolic steroids to easily be found on the internet, in gyms, and even in retail stores.
>
> Designer steroids are produced by reverse engineering existing illegal steroids and then slightly modifying the chemical composition, so that the resulting product is not on [DEA's] list of controlled substances. When taken by consumers, designer steroids can cause serious medical consequences, including liver injury and increased risk of heart attack and stroke. They may also lead to psychological effects such as aggression, hostility, and addiction.

160 Cong. Rec. S891–892 (daily ed. Feb. 11, 2014) (statement of Sen. Whitehouse); *accord* 160 Cong. Rec. H7460 (daily ed. Sept. 15, 2014) (statement of Rep. Pitts); *id.* at H7461 (statement of Rep. Christensen); *id.* (statement of Rep. Waxman).

Changes to the Definition of an Anabolic Steroid

To curtail the foregoing activity, DASCA amended the CSA definition of ''anabolic steroid'' by adding 22 new substances to the prior statutory list of anabolic steroids. *See* 21 U.S.C. 802(41)(A)(i)–(lxxiv). While the statute lists 25 substances, two of these substances are duplicates of substances previously listed in the regulatory definition of anabolic steroid, and one substance is included twice on the statutory list, bringing the actual number to 22 new specific substances. In particular, methasterone and prostanozol were included in the statute but were already listed, albeit under alternative chemical names, in the regulatory definition of anabolic steroid.[1] 4-Chloro-17α-methyl-androsta-1,4-diene-3,17β-diol is listed twice in the statute. *See id.* 802(41)(A)(liii), (lvii).

This rule revises the existing regulatory definition of ''anabolic steroid'' in 21 CFR 1300.01(b) to incorporate the revised statutory standard, moves the list of specifically named anabolic steroids from 21 CFR 1300.01(b) to 21 CFR 1308.13(f), and adds the 22 new substances included in DASCA to the relocated list at 21 CFR 1308.13(f).[2] In addition to incorporating the language of the statutory amendments of DASCA into DEA's regulations, this rule relocates and makes a number of organizational and typographical changes to the regulatory list of anabolic steroids to improve the list's clarity. These changes, however, do not add or remove any substances from this list beyond the 22 new substances added by DASCA or otherwise alter DASCA's language. DASCA expanded the definition of ''anabolic steroid'' to include a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed and is derived from, or has a chemical structure substantially similar to a listed anabolic steroid or steroids, if it: (1) has been created or manufactured with the intent of producing a substance that either promotes muscle growth or otherwise causes a pharmacological effect similar to that of testosterone; or (2) has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any pharmacological effect similar to that of testosterone. 21 U.S.C. 802(41)(C)(i). Unless otherwise excepted or listed in another schedule, all substances meeting the definition of ''anabolic steroid'' are controlled under schedule III of the CSA. *See id.* 812(c), Schedule III, (e); 21 CFR 1300.01(b), 1308.13(f). Thus, other substances that meet DASCA's revised definition of an anabolic steroid are also considered schedule III substances, even if they are not specifically listed in § 1308.13(f).

Under this modified definition, a substance shall not be considered to be a drug or hormonal substance if it: (1) is an herb or other botanical, a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical, or a combination of two or more such substances; (2) is a dietary ingredient for purposes of the Federal Food, Drug and Cosmetic Act (FD&C Act); and (3) is not anabolic or androgenic. 21 U.S.C. 802(41)(C)(ii). Any person claiming the benefit of exemption or exception under this definition shall bear the burden in administrative or judicial proceedings of going forward with evidence with respect to such exemption or exception in accordance with 21 U.S.C. 885(a). 21 U.S.C. 802(41)(C)(iii).

Changes to the Provisions Governing the Administrative Scheduling of Anabolic Steroids

To further diminish the ability of illicit manufacturers of anabolic steroids to circumvent the law by producing new designer substances with similar effects, DASCA also made it easier for DEA to add such substances to the list of anabolic steroids on a temporary and permanent basis. Specifically, DASCA added a new subsection to the CSA (21 U.S.C. 811(i)), which gives the Attorney General (and thus the Administrator of DEA by delegation) the authority to issue a temporary order adding a drug or substance to the definition of ''anabolic steroid'' upon the finding that: (A) the substance satisfies the criteria for being considered an anabolic steroid but is not already listed in 21 U.S.C. 802(41) or in the regulations of the Attorney General (in practice, the regulatory definition of ''anabolic steroid'' in 21 CFR 1300.01); and (B) such addition will assist in preventing abuse or misuse of the substance. 21 U.S.C. 811(i)(1). Such a temporary control order may last up to 24 months after the effective date, with a possible extension of 6 months, and may not take effect until 30 days after the date of the publication by the Attorney General of a notice in the **Federal Register** of the intention to issue such an order and the grounds upon which such an order is to be issued. 21 U.S.C. 811(i)(2). The Attorney General shall also transmit notice of a proposed order to the Secretary of Health and Human Services and take into consideration any comments submitted by the Secretary in response to that notice. 21 U.S.C. 811(i)(3). DASCA also gives the DEA the authority to issue, by rule, a permanent order adding a drug or other substance to the definition of an anabolic steroid if that drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41). 21 U.S.C. 811(i)(6).

Unlike scheduling under 21 U.S.C. 811(a), nothing in DASCA requires this rulemaking to take place on the record after opportunity for a hearing, and thus these permanent orders may be issued pursuant to the informal rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5 of the United States Code. *See* 5 U.S.C. 553(c).

New Labeling Requirements for Anabolic Steroids

To protect potential consumers from unknowingly ingesting anabolic steroids, and to ensure that all persons in the distribution chain identify those items that contain anabolic steroids, DASCA also added a labeling requirement to the CSA. This labeling provision states that it is unlawful to import, export, manufacture, distribute, or dispense—or possess with intent to manufacture, distribute, or dispense—an anabolic steroid or product containing an anabolic steroid, unless the product bears a label clearly identifying the anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC). 21 U.S.C. 825(e)(1). DASCA makes an exception to the IUPAC labeling requirement where the product is labeled in the manner required under the CSA and the FD&C Act; that is, the product is the subject of an approved application as described in 21 U.S.C. 355(b) or (j), or the product is

[1] Methasterone is currently identified as 2α,17α-dimethyl-5α-androstan-17β-ol-3-one in 21 CFR 1300.01(b)(''anabolic steroid'')(32), but as 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one in 21 U.S.C. 802(41)(A)(lviii). Prostanozol is currently identified as 17β-hydroxy-5α-androstano[3,2-c]pyrazole in 21 CFR 1300.01(b)(''anabolic steroid'')(58), but as [3,2-c]pyrazole-5α-androstan-17β-ol in 21 U.S.C. 802(41)(A)(lxxiv). This rule revises the regulatory list of anabolic steroids to include all these variations of the chemical names of methasterone and prostanozol.

[2] Although the list is being relocated from 21 CFR 1300.01(b) to 21 CFR 1308.13(f), all listed or defined anabolic steroids will maintain the same Controlled Substance Code Number, 4000.

exempt from the provisions of 21 U.S.C. 355 because it is intended solely for investigational use as described in 21 U.S.C. 355(i) and it is being used exclusively for the purposes of a clinical trial that is the subject of an effective investigational new drug application. *Id.* 825(e)(2).

DASCA also added new civil fine provisions for failure to comply with the labeling requirements:

- For a violation by an importer, exporter, manufacturer, or distributor (except as provided in the subsequent paragraph), up to $500,000 per instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute. 21 U.S.C. 842(c)(1)(C).
- In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of the labeling requirements at the retail level, up to $1,000 per violation. ''At the retail level'' refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container, or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level is a separate violation. 21 U.S.C. 842(c)(1)(D). Failure to comply with labeling requirements may be taken into account by DEA when issuing or revoking a registration.[3]

These penalty provisions are discussed here for the sake of completeness and given their close connection with other DASCA provisions. DEA is not amending its regulations to incorporate these civil fine provisions, as DEA's regulations do not address civil fines in general, making such amendment unnecessary.

Impact of Statutory Changes on Regulatory Requirements

In enacting DASCA and expanding the scope of substances that fall within the CSA definition of an anabolic steroid, Congress increased the number of substances that are schedule III controlled substances and subject to the corresponding provisions of the CSA. This law added 22 new substances to the list of schedule III controlled substances, which are included in 21 CFR 1308.13(f).

Since December 18, 2014, the manufacture, import, export, distribution, or sale of a newly listed anabolic steroid or a substance meeting the revised definition of an anabolic steroid, except by DEA registrants, has been a violation of the CSA that may result in imprisonment and fines. 21 U.S.C. 841, 960. Possession of the steroids unless legally obtained is also subject to criminal penalties. 21 U.S.C. 844. Importation of these schedule III steroids is illegal unless the person importing the steroids is registered with DEA as an importer or researcher and files the required declaration for each shipment. Illegal importation of a schedule III anabolic steroid is a violation of the CSA that may result in imprisonment and fines. 21 U.S.C. 960(a)(1).

Disposal of Anabolic Steroids

Persons who possess substances defined as anabolic steroids and who wish to dispose of them rather than becoming registered to handle them should contact their local DEA Diversion field office for assistance in disposing of these substances legally. The DEA Diversion field office will provide the person with instructions regarding the disposal. A list of local DEA Diversion field offices may be found at *https://apps2.deadiversion.usdoj.gov/contactDea/spring/fullSearch.*

Good Cause for Issuing This Rule as a Final Rule Without Notice and Comment

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553, including notice of proposed rulemaking and the opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds there is good cause within the meaning of the APA to issue these amendments as a final rule without notice and comment, because these amendments, as explained above, merely conform the implementing regulations with recent amendments to the CSA that have already taken effect (*see* 5 U.S.C. 553(b)(B), relating to notice and comment procedures). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Comm.* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States* v. *Cain,* 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, ''with regulations that merely restate or interpret statutory obligations,'' which do not); *Komjathy* v. *Nat'l Transp. Safety Bd.,* 832 F.2d 1294, 1296–97 (D.C. Cir. 1987) (per curiam) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority,'' notice-and-comment procedures are not required).

As DEA is simply incorporating the terms of DASCA into its regulations and making organizational and technical changes, publishing a notice of proposed rulemaking and soliciting public comment is unnecessary. The revised definition of ''anabolic steroid,'' the identification of 22 new specific substances as anabolic steroids, the new mechanism for temporary and permanent scheduling of anabolic steroids, and the revised labeling requirements for anabolic steroids have already been in effect since December 18, 2014. Moreover, while the list of anabolic steroids has been moved to § 1308.13(f), this change is a technical one; it imposes no new or substantive requirement on the public or DEA registrants. For the reasons discussed above, DEA also finds good cause exists to make this rule effective immediately upon publication. Therefore, we are issuing these amendments as a final rule, effective upon publication in the **Federal Register**. This rule constitutes final action on these changes under the APA, 5 U.S.C. 553.

Regulatory Analysis

As explained above, DEA is issuing this final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the DASCA. In issuing this final rule, DEA has not gone beyond the statutory text enacted by Congress. DEA's regulatory analysis is discussed below.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the

[3] See 21 U.S.C. 823(a), 824(a).

economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order. This rule is not a ''significant regulatory action'' under Executive Order 12866.

On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014 (DASCA) became law. The Act amended the Controlled Substances Act (CSA) to expand the general definition of ''anabolic steroid'' to include a broader range of substances, and to add 22 new specific substances to the list of named substances in the definition. The Act further provided a new mechanism for temporary and permanent scheduling of anabolic steroids as schedule III controlled substances, and added new labeling requirements for anabolic steroids, with penalties for violation of such requirements. These provisions of DASCA were self-implementing, and did not require any amendments to the Code of Federal Regulations in order to be effective. The 22 new specific substances that were not previously controlled and the other unnamed substances that meet DASCA's revised definition of anabolic steroid became schedule III substances with the passage of DASCA.

As stated above, the DEA is simply updating its regulations to be consistent with the exact terms of DASCA; this final rule does not change the legal status of these substances. Because the placement of these substances in schedule III, the revised general definition of ''anabolic steroid,'' the criteria and timeframes applicable to temporary and permanent scheduling of anabolic steroids, and the labeling requirements for anabolic steroids (with penalties for violation) have already been in effect since December 18, 2014, any economic impact of DASCA has already been absorbed by the economy.

Therefore, this final rule will have no economic impact. Accordingly, the DEA does not anticipate that this rulemaking will have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As explained above, the DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule.

Paperwork Reduction Act of 1995

This rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually 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. 2 U.S.C. 1532.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, the DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 18, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1302

Drug traffic control, Exports, Imports, Labeling, Packaging and containers.

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set forth above, 21 CFR parts 1300, 1302, and 1308 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended in paragraph (b) by revising the definition of ''Anabolic steroid'' as follows:

§ 1300.01 Definition relating to controlled substances.

* * * * *

(b) * * *

Anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes (but is not limited to) those substances listed in § 1308.13(f) of this chapter.

(1)(i) Except as provided in paragraph (1)(ii) of this definition, such term does not include an anabolic steroid that is expressly intended for administration

through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this definition.

(2)(i) Subject to paragraph (2)(ii) of this definition, a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in § 1308.13(f) of this chapter and is derived from, or has a chemical structure substantially similar to, one or more anabolic steroids listed in § 1308.13(f) of this chapter shall be considered to be an anabolic steroid for purposes of this chapter if—

(A) The drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(*1*) Promotes muscle growth; or

(*2*) Otherwise causes a pharmacological effect similar to that of testosterone; or

(B) The drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this definition if it—

(A) Is—

(*1*) An herb or other botanical;

(*2*) A concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(*3*) A combination of 2 or more substances described in paragraph (2)(ii)(A)(*1*) or (*2*) of this definition;

(B) Is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); and

(C) Is not anabolic or androgenic.

(iii) In accordance with 21 U.S.C. 885(a), any person claiming the benefit of an exemption or exception under paragraph (2)(ii) of this definition shall bear the burden of going forward with the evidence with respect to such exemption or exception.

* * * * *

PART 1302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1302 continues to read as follows:

Authority: 21 U.S.C. 821, 825, 871(b), 958(e).

■ 4. Section 1302.08 is added to read as follows:

§ 1302.08 False labeling of anabolic steroids.

(a) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(b)(1) A product described in paragraph (b)(2) of this section is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this section if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(2) A product is described in this paragraph (b)(2) if the product—

(i) Is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)); or

(ii) Is exempt from the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act relating to new drugs because—

(A) It is intended solely for investigational use as described in section 505(i) of the Federal Food, Drug, and Cosmetic Act; and

(B) Such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 5. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 6. Section 1308.13 is amended by revising paragraph (f) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(f) *Anabolic steroids.* Unless specifically excepted or unless listed in another schedule, any substance meeting the definition of anabolic steroid as set forth in § 1300.01 of this chapter, including any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers (4000):

(1) 5α-androstan-3,17-dione;

(2) 5α-androstan-3,6,17-trione;

(3) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(4) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(5) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene);

(6) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(7) 1-androstenedione (5α-androst-1-en-3,17-dione);

(8) 4-androstenedione (androst-4-en-3,17-dione);

(9) 5-androstenedione (androst-5-en-3,17-dione);

(10) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(11) boldenone (17β-hydroxyandrost-1,4-diene-3-one);

(12) boldione (androsta-1,4-diene-3,17-dione);

(13) 6-bromo-androsta-1,4-diene-3,17-dione;

(14) 6-bromo-androstan-3,17-dione;

(15) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(16) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(17) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;

(18) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;

(19) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;

(20) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);

(21) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);

(22) desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. ''madol'');

(23) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(24) Δ1-dihydrotestosterone (a.k.a. ''1-testosterone'') (17β-hydroxy-5α-androst-1-en-3-one);

(25) 3β,17β-dihydroxy-5α-androstane;

(26) 3α,17β-dihydroxy-5α-androstane;

(27) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;

(28) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);

(29) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;

(30) estra-4,9,11-triene-3,17-dione;

(31) 13β-ethyl-17β-hydroxygon-4-en-3-one;

(32) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(33) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);

(34) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);

(35) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]furazan);
(36) [3,2-c]furazan-5α-androstan-17β-ol;
(37) 18a-homo-3-hydroxy-estra-2,5(10)-dien-17-one;
(38) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);
(39) 4-hydroxy-androst-4-ene-3,17-dione;
(40) 17β-hydroxy-androstano[2,3-d]isoxazole;
(41) 17β-hydroxy-androstano[3,2-c]isoxazole;
(42) 3β-hydroxy-estra-4,9,11-trien-17-one;
(43) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);
(44) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);
(45) mesterolone (1α-methyl-17β-hydroxy-5α-androstan-3-one);
(46) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);
(47) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);
(48) methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one or 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one);
(49) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);
(50) 17α-methyl-androsta-1,4-diene-3,17β-diol;
(51) 17α-methyl-5α-androstan-17β-ol;
(52) 17α-methyl-androstan-3-hydroxyimine-17β-ol;
(53) 6α-methyl-androst-4-ene-3,17-dione;
(54) 17α-methyl-androst-2-ene-3,17β-diol;
(55) 17α-methyl-3β,17β-dihydroxy-5α-androstane;
(56) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(57) 17α-methyl-3β,17β-dihydroxyandrost-4-ene;
(58) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(59) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(60) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. ''17-α-methyl-1-testosterone'');
(61) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);
(62) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one);
(63) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(64) nandrolone (17β-hydroxyestr-4-en-3-one);
(65) 19-nor-4-androstenediol (3β,17β-dihydroxyestr-4-ene);
(66) 19-nor-4-androstenediol (3α,17β-dihydroxyestr-4-ene);
(67) 19-nor-5-androstenediol (3β,17β-dihydroxyestr-5-ene);
(68) 19-nor-5-androstenediol (3α,17β-dihydroxyestr-5-ene);
(69) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
(70) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
(71) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
(72) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(73) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(74) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(75) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(76) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-5α-androstan-3-one);
(77) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(78) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-5α-androstan-3-one);
(79) prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole or [3,2-c]pyrazole-5α-androstan-17β-ol);
(80) [3,2-c]pyrazole-androst-4-en-17β-ol;
(81) stanozolol (17α-methyl-17β-hydroxy-5α-androst-2-eno[3,2-c]-pyrazole);
(82) stenbolone (17β-hydroxy-2-methyl-5α-androst-1-en-3-one);
(83) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(84) testosterone (17β-hydroxyandrost-4-en-3-one);
(85) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one); and
(86) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one).

* * * * *

■ 7. Section 1308.50 is added to read as follows:

§ 1308.50 Temporary and permanent scheduling of recently emerged anabolic steroids.

(a) The Administrator may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Administrator finds that—

(1) The drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41) but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(2) Adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(b) An order issued under paragraph (a) of this section shall not take effect until 30 days after the date of the publication by the Administrator of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Administrator may, during the pendency of proceedings under paragraph (f) of this section, extend the temporary scheduling order for up to 6 months.

(c) The Administrator shall transmit notice of an order proposed to be issued under paragraph (a) of this section to the Secretary of Health and Human Services. In issuing an order under paragraph (a), the Administrator shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph (c).

(d) A temporary scheduling order issued under paragraph (a) of this section shall be vacated upon the issuance of a permanent scheduling order under paragraph (f) of this section.

(e) An order issued under paragraph (a) of this section is not subject to judicial review.

(f) The Administrator may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41). Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (a) of this section.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9515]

RIN 1545–BH20

Guidance Under Section 1502; Amendment of Matching Rule for Certain Gains on Member Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to Treasury Decision 9515, which was published in the **Federal Register** for Friday, March 4, 2011.