proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Pratt & Whitney: Docket No. FAA–2011–1194; Directorate Identifier 2011–NE–36–AD.

(a) Comments Due Date

We must receive comments by January 23, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney PW4050, PW4052, PW4056, PW4056(–3), PW4156, PW4060, PW4060(–3), PW4060A, PW4152, PW4152(–3), PW4156A, PW4158, PW4158(–3), PW4460, PW4460(–3), PW4462, and PW4462(–3) turbofan engines.

(d) Unsafe Condition

This AD was prompted by reports of five engine in-flight shutdowns and seven unplanned engine removals due to clogging of No. 4 bearing compartment oil pressure and scavenge tubes. We are issuing this AD to prevent an engine fire, a fractured fan drive shaft, and damage to the airplane.

(e) Compliance

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

(f) Inspection and Cleaning of No. 4 Bearing Compartment for Coking

(1) Within 1,000 cycles-in-service (CIS) after the effective date of this AD, initially inspect and clean the No. 4 bearing compartment in accordance with Accomplishment Instructions, paragraphs 2.A. through 2.A.(4)(b)3 of Pratt & Whitney Alert Service Bulletin No. PW4ENG–A72–436, Revision 6, dated September 30, 1999.

(2) Thereafter, within every additional 1,000 CIS, perform the inspection and cleaning specified in paragraph (f)(1) of this AD.

(g) Modification To Stop Buildup of Coking in the No. 4 Bearing Compartment

(1) At the next engine visit to a maintenance facility that is capable of performing the following on-wing method or in-shop method of modification to the No. 4 bearing compartment, but not to exceed 5 years after the effective date of this AD, do the following:

(i) Replace the No. 4 bearing packing transfer tube assembly;

(ii) Replace the No. 4 bearing internal scavenge tube assembly;

(iii) Remove the No. 4 bearing shield, and the No. 4 bearing shield option; and

(iv) Install new No. 4 bearing shield options.

(2) For doing the on-wing method of the modification, do the work in accordance with Accomplishment Instructions, Paragraphs 2.A. through 2.A.(9)(a)3d of Pratt & Whitney Service Bulletin (SB) No. PW4ENG–72–472, Revision 5, dated April 14, 1998.

(3) For doing the in-shop method of the modification, do the work in accordance with Paragraphs 2.B. through 2.B.(2)(f)2d of Pratt & Whitney SB No. PW4ENG–72–472, Revision 5, dated April 14, 1998.

(h) Rerouting of the No. 4 Bearing Pressure and Scavenge Tubes

(1) At the next shop visit at which the engine is sufficiently disassembled to perform the rerouting, but not to exceed 5 years after the effective date of this AD, do the following:

(i) Modify the turbine exhaust case to relocate the No. 4 bearing pressure and scavenge tube ports;

(ii) Replace the internal No. 4 bearing pressure and scavenge tubes;

(iii) Modify or replace the turbine case cooling brackets to support the new No. 4 bearing pressure and scavenge tubes;

(iv) Replace the turbine case manifolds as necessary; and

(v) Install the new brackets and clamps to support the new routing configuration.

(2) Do the work specified in paragraph (h) of this AD in accordance with Accomplishment Instructions paragraph 2 of Pratt & Whitney SB No. PW4ENG–79–76, Revision 4, dated February 14, 2002.

(i) Terminating Action to the Repetitive Inspections and Cleaning

Performing the modifications specified in both paragraphs (g) and (h), of this AD is terminating action to the repetitive inspections and cleanings specified in paragraph (f)(2) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

(1) For more information about this AD, contact Stephen Sheely, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; *phone:* (781) 238–7750; fax: (781) 238–7199; *email: stephen.k.sheely@faa.gov.*

(2) For service information identified in this AD, contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone: (860) 565–8770; fax: (860) 565–4503. You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Issued in Burlington, Massachusetts, on November 15, 2011.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–30138 Filed 11–22–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1300

[Docket No. DEA–341P]

RIN 1117–AB31

Classification of Two Steroids, Prostanozol and Methasterone, as Schedule III Anabolic Steroids Under the Controlled Substances Act

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This Notice of Proposed Rulemaking (NPRM) proposes to classify the following two steroids as ''anabolic steroids'' under the Controlled Substances Act (CSA): prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one). The Drug Enforcement Administration (DEA) believes that this action is necessary to prevent the abuse and trafficking of

these steroids. If the regulations are amended, these steroids will be listed as Schedule III controlled substances subject to the regulatory control provisions of the CSA.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before January 23, 2012. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–341'' on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/OD, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

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. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information'' paragraph.

Background Information

On November 29, 1990, the President signed into law the Anabolic Steroids Control Act of 1990 (Title XIX of Pub. L. 101–647), which became effective February 27, 1991. This law established and regulated anabolic steroids as a class of drugs under Schedule III of the CSA. As a result, a new anabolic steroid is not scheduled according to the procedures set out in 21 U.S.C. 811, but can be administratively classified as an anabolic steroid through the rulemaking process by adding the steroid to the regulatory definition of an anabolic steroid in 21 CFR 1300.01(b)(4).

On October 22, 2004, the President signed into law the Anabolic Steroid Control Act of 2004 (Pub. L. 108–358), which became effective on January 20, 2005. Section 2(a) of the Anabolic Steroid Control Act of 2004 amended 21 U.S.C. 802(41)(A) by replacing the existing definition of ''anabolic steroid.'' The Anabolic Steroid Control Act of 2004 classifies a drug or hormonal substance as an anabolic steroid if the following four criteria are met: (A) The substance is chemically related to testosterone; (B) the substance is pharmacologically related to testosterone; (C) the substance is not an estrogen, progestin, or a corticosteroid; and (D) the substance is not dehydroepiandrosterone (DHEA). Any substance that meets the criteria is considered an anabolic steroid and must be listed as a Schedule III controlled substance. DEA believes that prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) meet this definition of ''anabolic steroid,'' and is proposing that they be added to the list of anabolic steroids in 21 CFR 1300.01(b)(4).

Anabolic steroids are a class of drugs structurally related to the endogenous hormone testosterone that exert androgenic (masculinizing) as well as anabolic (body building) effects. These effects are mediated primarily through binding of the anabolic steroid to the androgen receptor in target tissues (Evans, 2004). Anabolic effects include promotion of protein synthesis in skeletal muscle and bone, while the androgenic effects are characterized by the development of male secondary sexual characteristics such as hair growth, deepening of the voice, glandular activity, thickening of the skin, and central nervous system effects, to name a few (Kicman, 2008). Anabolic efficacy is characterized by positive nitrogen balance and protein metabolism, resulting in increases in protein synthesis and lean body mass (Evans, 2004). These effects often come at a cost to the healthy individual who experiences clear physical and psychological complications (Trenton and Currier, 2005; Brower, 2002; Hall *et al.,* 2005).

In the United States, only a small number of anabolic steroids are approved for either human or veterinary use. Approved medical uses for anabolic steroids include treatment of androgen deficiency in hypogonadal males, adjunctive therapy to offset protein catabolism associated with prolonged administration of corticosteroids, treatment of delayed puberty in boys, treatment of metastatic breast cancer in women, and treatment of anemia associated with specific diseases (*e.g.,* anemia of chronic renal failure, Fanconi's anemia, and acquired aplastic anemia). However, with the exception of the treatment of male hypogonadism, anabolic steroids are not the first-line treatment due to the availability of other preferred treatment options. DEA is not aware of any legitimate medical use or New Drug Applications (NDA) for the two substances that DEA is proposing to classify by this NPRM as anabolic steroids under the definition set forth under 21 U.S.C. 802(41)(A). Moreover, DEA has not been able to identify any chemical manufacturers currently using these substances as intermediates in their manufacturing process(es).

Adverse health effects are associated with abuse of anabolic steroids and

depend on several factors (*e.g.,* age, sex, anabolic steroid used, the amount used, and the duration of use) (Hall and Hall, 2005; Quaglio *et al.,* 2009). These include cardiovascular, dermatological, behavioral, hepatic, and gender specific endocrine side effects. Anabolic steroids have direct and indirect impact on the developing adolescent brain and behavior (Sato *et al.,* 2008). Furthermore, adolescent abuse of anabolic steroids may result in stunted growth due to premature closure of the growth plates in long bones. In adolescent boys, anabolic steroid abuse can cause precocious sexual development. In both girls and women, anabolic steroid abuse induces permanent physical changes such as deepening of the voice, increased facial and body hair growth, menstrual irregularities, and clitoral hypertrophy. In men, anabolic steroid abuse can cause testicular atrophy, decreased sperm count, and sterility. Gynecomastia (*i.e.,* enlargement of the male breast tissue) can develop with the abuse of those anabolic steroids with estrogenic actions. In both men and women, anabolic steroid abuse can damage the liver and may result in high cholesterol levels, which may increase the risk of strokes and cardiovascular heart attacks. Furthermore, anabolic steroid abuse is purported to induce psychological effects such as aggression, increased feelings of hostility, and psychological dependence and addiction (Brower, 2002; Kanayama *et al.,* 2008). Upon abrupt termination of long-term anabolic steroid abuse, a withdrawal syndrome may appear including severe depression. Additionally, polysubstance abuse is routinely associated with anabolic steroid abuse, where ancillary drugs, including recreational and prescription drugs, are abused in response to unwanted side effects (Hall *et al.,* 2005; Parkinson *et al.,* 2005; Skarberg *et al.,* 2009).

A review of the scientific literature finds adverse health effects including liver toxicity with renal failure reported in conjunction with methasterone abuse (Shah *et al.,* 2008; Jasiurkowski *et al.,* 2006; Singh *et al.,* 2009; Nasr and Ahmad, 2008; and Krishnan *et al.,* 2009). In March 2006, the U.S. Food and Drug Administration (FDA) issued a Warning Letter in response to adverse health effects associated with the product Superdrol (methasterone). In July 2009, FDA issued a warning regarding bodybuilding products containing steroid or steroid-like substances. In this warning, a product containing the THP ether derivative of prostanozol was named in conjunction with other products presenting safety concerns.

Evaluation of Statutory Factors for Classification as an Anabolic Steroid

DEA is proposing by this NPRM to classify prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) as anabolic steroids under the definition set forth under 21 U.S.C. 802(41)(A). As noted previously, a drug or hormonal substance is classified as an anabolic steroid by meeting the following four definitional requirements: (A) The substance is chemically related to testosterone; (B) the substance is pharmacologically related to testosterone; (C) the substance is not an estrogen, progestin, or corticosteroid; and (D) the substance is not DHEA.

(A) Chemically Related to Testosterone

To classify a substance as an anabolic steroid, a substance must be chemically related to testosterone. A structure activity relationship (SAR) evaluation for each substance compared the chemical structure of the steroid to that of testosterone. Substances with a structure similar to that of testosterone are predicted to possess comparable pharmacological and biological activity.

Prostanozol is also known by the following name: 17β-hydroxy-5α-androstano[3,2-c]pyrazole. DEA determined that the chemical structure of prostanozol is similar to testosterone, differing by only the attachment of a pyrazole ring at carbon 2 (C2) and carbon 3 (C3) positions of the androstane skeleton, replacing the C3-keto group and the lack of a double bond between carbon 4 (C4) and carbon 5 (C5) positions. Similar modifications to testosterone's chemical structure have been documented and, in general, they have been found to be well tolerated, displaying both anabolic and androgenic activity (Fragkaki *et al.,* 2009; Vida, 1969). Clinton and coworkers, in their synthesis of prostanozol, described the modification as a fusion of a pyrazole ring to the androstane steroidal nucleus at C2 and C3 (Clinton *et al.,* 1961). Further analysis finds the chemical structure of prostanozol to be very similar to the anabolic steroid stanozolol. The two structures differ only about a 17α-methyl group (alpha methyl group attached to carbon 17).

Methasterone is known by the following chemical names: 2α,17α-dimethyl-5α-androstan-17β-ol-3-one; 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one; 17α-methyl-drostanolone; methasteron; methyldrostanolone; 2α,17α-dimethyldihydrotestosterone; and 2α,17α-dimethyl-etiocholan-17β-ol-3-one. DEA has determined that the chemical structure of methasterone is chemically related to testosterone. The chemical structure of methasterone differs from testosterone by the following three chemical groups: an alpha methyl group at carbon 17 (C17), an alpha methyl group at C2, and the lack of a double bond between spanning C4 and C5. Removal of the C4–C5 double bond (A-ring) and methylation at the C2 and C17 positions has been shown to increase anabolic activity (Zaffroni, 1960; Fragkaki *et al.,* 2009). Furthermore, methyl group substitution at the C2 and C17 has been reported to impair aromatization, thus, prolonging the anabolic effect (Fragkaki *et al.,* 2009).

(B) Pharmacologically Related to Testosterone

A substance must also be pharmacologically related to testosterone (*i.e.,* produce similar biological effects) to be classified as a Schedule III anabolic steroid. The pharmacology of a steroid, as related to testosterone, can be established by performing one or more of the following androgenic and anabolic activity assays: ventral prostate assay, seminal vesicle assay, levator ani assay, and androgen receptor binding and efficacy assays. These assays are described below.

Ventral Prostate Assay, Seminal Vesicle Assay, and Levator Ani Assay: The classic scientific procedure for evaluating androgenic (masculinizing) and anabolic (muscularizing) effects of a steroid is the ventral prostate assay, seminal vesicle assay, and levator ani assay. This testing paradigm allows for the direct comparison to testosterone. Select male accessory tissues (*i.e.,* the ventral prostate, seminal vesicles, and levator ani muscle) are testosterone sensitive, specifically requiring testosterone to grow and remain healthy. Upon the removal of the testes (*i.e.,* castration), the primary endogenous source of testosterone is eliminated causing the atrophy of the ventral prostate, seminal vesicles, and levator ani muscle (Eisenberg *et al.,* 1949; Nelson *et al.,* 1940; Scow, 1952; Wainman and Shipounoff, 1941). Numerous scientific studies have demonstrated the ability of exogenous testosterone or a pharmacologically similar steroid administered to rats following castration to maintain the normal weight and size of all three testosterone sensitive organs (Biskind and Meyer, 1941; Dorfman and

Dorfman, 1963; Dorfman and Kincl, 1963; Kincl and Dorfman, 1964; Nelson *et al.,* 1940; Scow, 1952; Wainman and Shipounoff, 1941). Thus, a steroid with testosterone-like activity will also prevent the atrophy of these three testosterone-dependent organs in castrated rats.

Castrated male rats are administered the steroid for a number of days, then the rats are euthanized and the previously described tissues are excised and weighed. Tissue weights from the three animal test groups are compared, castrated animals alone, castrated animals receiving the steroid, and healthy intact animals (control), to assess anabolic and androgenic activity. A reduction in tissue weights relative to the control group suggests a lack of androgenic and/or anabolic activity. An increase in tissue weights relative to the castrated rats receiving no steroid suggests an androgenic and/or anabolic effect.

Androgen Receptor Binding and Efficacy Assay: Anabolic steroids bind with the androgen receptor to exert their biological effect. Affinity for the receptor is evaluated in the receptor binding assay, while the transactivation (functional) assay provides additional information as to both affinity and ability to activate the receptor. Receptor binding and transactivation studies are valuable tools in evaluating pharmacological activity and drawing comparisons to other substances. A steroid displaying affinity for the androgen receptor and properties of being an agonist in transactivation studies is determined to be pharmacologically similar to testosterone.

Studies used to evaluate anabolic steroids are the androgen receptor binding assay and the androgen receptor transactivation assay. Both are well-established and provide significant utility in evaluating steroids for affinity to their biological target and the modulation of activity. The androgen receptor binding assay provides specific detail as to the affinity of a steroid for the androgen receptor (biological target of anabolic steroids). To assess further whether the steroid is capable of activating the androgen receptor, the androgen receptor transactivation assay evaluates the binding of a steroid to the androgen receptor and subsequent interaction with DNA. In this study, transcription of a reporter gene provides information as to a steroid's ability to modulate a biological event. This activity measurement provides information as to the potency of a steroid to bind to a receptor and either initiate or inhibit the transcription of the reporter gene. The androgen receptor binding assay and androgen receptor transactivation assay are highly valuable tools in assessing the potential activity of a steroid and comparing the activity to testosterone.

Results of the Androgenic and Anabolic Activity Assays

DEA reviewed the published scientific literature, and pharmacological studies were undertaken to collect additional information on prostanozol and methasterone in several different androgenic and anabolic activity assays.

Findings from these studies indicate that in addition to being structurally similar to testosterone, prostanozol and methasterone have similar pharmacological activity as testosterone.

Prostanozol

The chemical synthesis and anabolic and androgenic effects of prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) were published in 1961 (Clinton *et al.,* 1961). Clinton and coworkers evaluated the anabolic activity by means of nitrogen balance and androgenic activity based on weight changes of the ventral prostrate of prostanozol upon subcutaneous administration to rats with the reference standard testosterone propionate. The potency ratio of anabolic activity to androgenic activity for prostanozol was reported to be eight (Clinton *et al.,* 1961). In another study, prostanozol was reported to have approximately the same relative binding affinity for human sex steroid binding protein as testosterone (Cunningham *et al.,* 1981).

To build on these findings, a pharmacological study [1] was conducted to evaluate the anabolic and androgenic effects of prostanozol in castrated male rats. Results were compared to testosterone by a similar protocol. Administration of prostanozol to castrated male rats by subcutaneous injection prevented the atrophy (loss in weight) of the ventral prostate, seminal vesicles, and levator ani muscle.[1] These testosterone sensitive tissues experienced increases in weight comparable to testosterone in castrated male rats. Results from this study support that prostanozol possesses both androgenic and anabolic activity. Additional studies were conducted to further assess prostanozol's anabolic effect. In a competitive binding assay, prostanozol was found to possess affinity for the androgen receptor comparable to testosterone.[1] In the androgen receptor transactivation assay, prostanozol displayed increased activity relative to testosterone.[1] Effects elicited by prostanozol in this transactivation assay were consistent and comparable to those of testosterone. Taken together, data from in vitro and in vivo assays indicate the pharmacology of prostanozol to be similar to testosterone.

Methasterone

The synthesis of methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) was reported in 1956 and the anabolic activity in 1959 (Ringold and Rosenkranz, 1956; Ringold *et al.,* 1959). Methasterone was described as a potent anabolic agent exhibiting weak androgenic activity in the castrated male rat (Ringold *et al.,* 1959). Zaffaroni and coworkers reported methasterone possessed one-fifth the androgenic activity and four times the anabolic activity of the anabolic steroid methyltestosterone, when administered orally to the experimental animal (Zaffaroni *et al.,* 1960).

Additional pharmacological studies were undertaken to further evaluate the androgenic and anabolic effects of methasterone. [1] Methasterone was administered subcutaneously and orally to castrated male rats. By both routes of administration, methasterone prevented the atrophy (loss in weight) of ventral prostate, seminal vesicles, and levator ani muscle. Tissue weight increases for the castrated methasterone-treated animals were comparable to the castrated rats treated with testosterone and methyltestosterone. These results were consistent with earlier findings that methasterone is anabolic and androgenic (Zaffaroni, 1960; Ringold *et al.,* 1959). Functional assays were also undertaken to further evaluate methasterone.[1] Methasterone displayed affinity for the androgen receptor comparable to testosterone in a competitive binding assay.[1] In the androgen receptor transactivation assay, methasterone displayed increased activity relative to testosterone.[1] Effects elicited by methasterone in the androgen transactivation assay were consistent and comparable to those of testosterone. Collectively, in vivo and in vitro results indicate that the pharmacology of methasterone is similar to testosterone.

(C) Not Estrogens, Progestins, and Corticosteroids

DEA has determined that prostanozol and methasterone are unrelated to estrogens, progestins, and corticosteroids. DEA evaluated the SAR for each of the substances. The chemical structure of each substance was

[1] 2009 BIOQUAL, Inc. study commissioned by the National Institutes of Health on behalf of DEA.

compared to that of estrogens, progestins, and corticosteroids, since chemical structure can be related to its pharmacological and biological activity. DEA found that these two substances lack the necessary chemical structures to impart significant estrogenic activity (*e.g.,* aromatic A ring) (Duax *et al.,* 1988; Jordan *et al.,* 1985; Williams and Stancel, 1996), progestational activity (*e.g.,* 17β-alkyl group) (Williams and Stancel, 1996), or corticosteroidal activity (*e.g.,* 17β-ketone group or 11β-hydroxyl group) (Miller *et al.,* 2002). Furthermore, methasterone was reported to display anti-estrogenic activity in mouse assay to assess estrogen stimulated uterine growth (Dorfman *et al.,* 1961). To assess the estrogenic, progestational, and corticosteroid activity of prostanozol and methasterone, these substances were evaluated in receptor binding and functional transactivation assays. Prostanozol and methasterone showed low binding affinity for the estrogen, progesterone, and glucocorticoid receptors. Furthermore, these steroids displayed low to no transactivation mediated by the estrogen receptors, progesterone receptors, or glucocorticoid receptors. Therefore, based on these data, prostanozol and methasterone are not estrogens, progestins, or corticosteroids and these anabolic steroids are not exempt from control on this basis.

(D) Not Dehydroepiandrosterone

Dehydroepiandrosterone, also known as DHEA, is exempt from control as an anabolic steroid by definition (21 U.S.C. 802(41)(A)). Prostanozol and methasterone are not dehydroepiandrosterone and therefore, are not exempt from control on this basis.

Conclusion

Therefore, based on the above, DEA concludes that prostanozol and methasterone meet the CSA definition of ''anabolic steroid'' because each substance is: (A) Chemically related to testosterone; (B) pharmacologically related to testosterone; (C) not an estrogen, progestin, or a corticosteroid; and (D) not DHEA (21 U.S.C. 802(41)). All anabolic steroids are classified as Schedule III controlled substances (21 U.S.C. 812). Once a substance is determined to be an anabolic steroid, DEA has no discretion regarding the scheduling of these substances. As discussed further below, all requirements pertaining to controlled substances in Schedule III would pertain to these substances.

Impact of Proposed Rule and Effect of Classifying These Substances as Anabolic Steroids

If this rulemaking is finalized as proposed, DEA will classify prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) as Schedule III anabolic steroids. If classified as Schedule III anabolic steroids, any person who manufactures, distributes, dispenses, imports, or exports prostanozol or methasterone or who engages in research or conducts instructional activities with respect to these two substances would be required to obtain a Schedule III registration in accordance with the CSA and its implementing regulations. Manufacturers and importers of these two substances would be required to register with DEA and would be permitted to distribute these substances only to other DEA registrants. Only persons registered as dispensers would be allowed to dispense these substances to end users. The CSA defines a practitioner as ''a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' 21 U.S.C. 802(21). At present, there are no approved medical uses for these two substances. Until a manufacturer applies to the FDA and gains approval for products containing these substances, no person may dispense them in response to a prescription.

Manufacture, import, export, distribution, or sale of prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) except by DEA registrants, would become a violation of the CSA that may result in imprisonment and fines (see, *e.g.,* 21 U.S.C. 841, 960). Possession of these two steroids, unless legally obtained, would also become subject to criminal penalties (21 U.S.C. 844).

In addition, under the CSA, these two substances could be imported only for medical, scientific, or other legitimate uses (21 U.S.C. 952(b)) under an import declaration filed with DEA (21 CFR 1312.18). Importation of these substances would be illegal unless the person importing these substances is registered with DEA as an importer or researcher and files the required declaration for each shipment. An individual who purchases either of these substances directly from foreign companies and has them shipped to the United States will be considered to be importing even if the steroids are intended for personal use. Illegal importation of these substances would be a violation of the CSA that may result in imprisonment and fines (21 U.S.C. 960).

Requirements for Handling Substances Defined as Anabolic Steroids

Upon consideration of public comments from this NPRM, DEA may issue a final rule classifying prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) as anabolic steroids. If classified as anabolic steroids, prostanozol and methasterone would become subject to CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importation, and exportation of a Schedule III controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, or engages in research or conducts instructional activities with a substance defined as an anabolic steroid, or who desires to engage in such activities, would be required to be registered to conduct such activities with Schedule III controlled substances in accordance with 21 CFR Part 1301.

Security. Substances defined as anabolic steroids would be subject to Schedule III–V security requirements and would be required to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of substances defined as anabolic steroids would be required to comply with requirements of 21 CFR 1302.03–1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of any substance defined as an anabolic steroid would be required to keep an inventory of all stocks of the substances on hand pursuant to 21 U.S.C. 827 and 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in Schedule III for any substance defined as an anabolic steroid would be required to conduct an inventory of all stocks of the substances on hand at the time of registration.

Records. All registrants would be required to keep records, as generally provided in 21 U.S.C. 827(a) and specifically pursuant to 21 CFR 1304.03, 1304.04, 1304.05, 1304.21, 1304.22, 1304.23 and 1304.26.

Prescriptions. All prescriptions for these Schedule III substances or for products containing these Schedule III substances would be required to be issued pursuant to 21 U.S.C. 829(b) and 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for these Schedule III compounds or for products containing these Schedule III substances, if authorized for refilling, would be limited to five refills within six months of the date of issuance of the prescription. Controlled substance dispensing via the Internet would have to comply with 21 U.S.C. 829(e).

Importation and Exportation. All importation and exportation of any substance defined as an anabolic steroid would be required to be in compliance with 21 U.S.C. 952(b) and 953(e) and 21 CFR Part 1312.

Criminal Liability. Any activity with any substance defined as an anabolic steroid not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act would be unlawful.

Disposal of Anabolic Steroids

If this regulation is finalized as proposed, persons who possess substances that become classified 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 *http://www.deadiversion.usdoj.gov.*

Regulatory Analyses

Regulatory Flexibility Act

The Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). DEA is not able to determine whether this regulation, if promulgated as a Final Rule, will not have a significant economic impact on a substantial number of small entities. DEA has not identified any company based in the United States that manufactures or distributes these substances. Thus, DEA does not believe this proposed rule would have a significant economic impact on a substantial number of small entities. Because DEA is unable to determine whether this regulation as proposed would have a significant economic impact on a substantial number of small entities, DEA seeks comment on whether this regulation, if promulgated as a Final Rule, will have a significant economic impact on a substantial number of small entities.

As of March 2010, DEA had identified approximately 75 dietary supplements that were currently or had been promoted for building muscle and increasing strength that purported to contain prostanozol or methasterone. Thirteen dietary supplements were purported to contain prostanozol and 62 dietary supplements were purported to contain methasterone. These dietary supplements are marketed and sold over the Internet.

The manufacturers and distributors of dietary supplements purported to contain prostanozol and methasterone also sell a variety of other dietary supplements. DEA has identified a substantial number of Internet distributors that sell these dietary supplements. However, these distributors also sell a variety of other nutritional products. Without information on the percentage of revenues derived from these dietary supplements, DEA is not able to determine the economic impact of the removal of these dietary supplements alone on the business of the firms. These steroids have been the focus of warning letters issued by the FDA. However, products continue to be marketed despite these warnings. DEA has not been able to identify any chemical manufacturers that are currently using these substances as intermediates in their manufacturing process(es).

As of March 2010, DEA had identified 13 chemical manufacturers and distributors that sell at least one of the two steroids addressed in this NPRM. Most of these companies are located in China and sell a variety of other anabolic steroids. DEA notes that, as the vast majority of entities handling these substances are Internet based, it is virtually impossible to accurately quantify the number of persons handling these substances at any given time. DEA has not identified any company based in the United States that manufactures or distributes these substances. DEA notes, upon placement into Schedule III, these substances may be used for analytical purposes.

Executive Orders 12866 and 13563

This rulemaking has been drafted in accordance with the principles of Executive Order 12866, 1(b), as reaffirmed by Executive Order 13563. This rule is not a significant regulatory action but has been reviewed by the Office of Management and Budget. As discussed above, the effect of this rule would be to remove products containing these substances from the over-the-counter marketplace. DEA has no basis for estimating the size of the market for these products. DEA notes, however, that virtually all of the substances are imported. According to U.S. International Trade Commission data, the import value of all anabolic steroids in 2009 was $5.9 million. These two substances would be a subset of those imports. The total market for products containing these substances, therefore, is probably quite small. Moreover, DEA believes that the importation of these two substances is for illegitimate purposes.

The benefit of controlling these substances is to remove from the marketplace substances that have dangerous side effects and no legitimate medical use in treatment in the United States. As discussed in detail above, these substances can produce serious health effects in adolescents and adults. If medical uses for these substances are developed and approved, the drugs would be available as Schedule III controlled substances in response to a prescription issued by a medical professional for a legitimate medical purpose. Until that time, however, this action would bar the importation, exportation, and sale of these two substances except for legitimate research or industrial uses.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This proposed rule will not have Tribal implications and will not impose substantial direct compliance costs on Indian Tribal governments.

Paperwork Reduction Act

This rule proposes to regulate two anabolic steroids, which are neither approved for medical use in humans nor approved for administration to cattle or

other non-humans. Under this proposal, only chemical manufacturers who may use these substances as chemical intermediates for the synthesis of other steroids would be required to register with DEA under the CSA. However, DEA has not been able to identify any chemical manufacturers that are currently using these substances as intermediates in their manufacturing process(es). Although this proposal is unlikely to impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521, DEA is nevertheless seeking input from the chemical industry on any manufacturing process(es) that may be affected.

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 $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

List of Subjects in 21 CFR Part 1300

Chemicals, Drug traffic control.

For the reasons set out above, 21 CFR part 1300 is proposed to be 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, 829, 871(b), 951, 958(f).

2. Section 1300.01 is proposed to be amended by:

A. Redesignating paragraphs (b)(4)(xxxii) through (b)(4)(lxiii) as (b)(4)(xxxiii) through (b)(4)(lxiv),

B. Adding a new paragraph (b)(4)(xxxii),

C. Further redesignating newly designated paragraphs (b)(4)(lviii) through (b)(4)(lxiv) as (b)(4)(lix) through (b)(4)(lxv), and

D. Adding new paragraph (b)(4)(lviii).

The additions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(4) * * *

(xxxii) Methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one)

* * * * *

(lviii) Prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole)

* * * * *

Dated: November 8, 2011.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–149625–10]

RIN 1545–BK03

Application of the Segregation Rules to Small Shareholders

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 382 of the Internal Revenue Code (Code). These proposed regulations provide guidance regarding the application of the segregation rules to public groups under section 382 of the Code. These regulations affect corporations.

DATES: Written or electronic comments and requests for a public hearing must be received by February 21, 2012.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–149625–10), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–149625–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov/* (IRS REG–149625–10).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Stephen R. Cleary, (202) 622–7750; concerning submission of comments or to request a public hearing, Oluwafunmilayo (Funmi) P. Taylor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

1. Segregation and Aggregation—Statute, Legislative History, and Current Regulations

Section 382 imposes a limitation on a corporation's use of net operating loss carryovers following a change in ownership. The legislative history explains that a limitation is necessary following a change in ownership because new shareholders otherwise would have an opportunity to contribute income-producing assets (or divert income opportunities) to the corporation, thus inappropriately accelerating the use of net operating loss carryovers. The section 382 limitation is intended to prevent a corporation from obtaining greater loss utilization than it could have achieved absent a change in ownership. S. Rep. No. 99–313 at 232 (1986).

A loss corporation has an ownership change if the percentage of stock of a loss corporation that is owned by one or more 5-percent shareholders has increased by more than 50 percentage points over the lowest percentage of stock of the loss corporation owned by such shareholders at any time during the testing period (generally, a three-year period). For purposes of section 382, the attribution rules of section 318(a)(2) apply, without limitation, to treat individuals as the owners of loss corporation stock. Pursuant to section 382(g)(4)(A), individual shareholders who own less than five percent of a loss corporation are aggregated and treated as a single 5-percent shareholder (a public group).

The regulations extend the public group concept to situations in which a loss corporation is owned by one or more entities, as defined in § 1.382–3(a) (generally, partnerships, corporations, estates, and trusts). If an entity directly or indirectly owns five percent or more of the loss corporation, that entity has its own public group if its owners who are not 5-percent shareholders own, in the aggregate, five percent or more of the loss corporation. (Such an entity is referred to as a 5-Percent Entity in this preamble.)

The segregation rules, which are generally contained in § 1.382–2T(j), and the exceptions thereto, which are generally contained in § 1.382–3(j), apply to certain transactions affecting ownership by the loss corporation's direct public group and by the public groups of a 5-Percent Entity. The application of the segregation rules results in the creation of a new public group in addition to the one (or more) that existed previously. That new group is treated as a new 5-percent shareholder that increases its ownership interest in the loss corporation.

Section 382(g)(4)(B) mandates application of the segregation rules to transactions constituting equity structure shifts of the loss corporation. Generally, equity structure shifts are acquisitive asset reorganizations and recapitalizations under section 368. Section 382(g)(3)(B) provides regulatory authority to treat public offerings and similar transactions as equity structure shifts. Pursuant to that authority, the current segregation rules, subject to the cash issuance and small issuance exceptions (described in this preamble), treat issuances of stock under section 1032, redemptions, and redemption-like transactions as segregation events. The segregation rules also apply to transfers of loss corporation stock by an individual 5-percent shareholder to public shareholders and a 5-Percent Entity's transfer of loss corporation stock to public shareholders.

The small issuance and cash issuance exceptions exempt certain amounts of stock issuances from the segregation rules. Generally, the small issuance exception exempts the total amount of stock issued during a taxable year to the extent it does not exceed 10 percent of the total value of the corporation's