I. 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 Controlled Substances Act (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 boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione 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 with a basic steroid ring structure that produces anabolic and androgenic effects. The prototypical anabolic steroid is testosterone. Anabolic effects include promoting the growth of muscle. The androgenic effects consist of promoting the development of male secondary sexual characteristics such as facial hair, deepening of the voice, and thickening of the skin.

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 three 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 effects are associated with the use or abuse of anabolic steroids. These effects depend on several factors (e.g., age, sex, anabolic steroid used, the amount used, and the duration of use). In early adolescents, the use of testosterone and other anabolic steroids that have estrogenic effects can cause precocious sexual development. In adolescent boys, anabolic steroid use can cause precocious sexual development. In both girls and women, anabolic steroid use induces permanent physical changes such as deepening of the voice, increased facial and body hair growth, and the lengthening of the clitoris. In men, anabolic steroid use can cause shrinkage of the testicles, decreased sperm count, and sterility.

Gynecomastia (i.e., enlargement of the male breast tissue) can develop with the use of those anabolic steroids with estrogenic actions. In both men and women, anabolic steroid use can damage the liver and can cause high cholesterol levels, which may increase the risk of strokes and heart attacks. Furthermore, anabolic steroid use is purported to induce psychological effects such as aggression, increased feelings of hostility, and psychological dependence and addiction. Upon abrupt termination of long-term anabolic steroid use, a withdrawal syndrome may appear including severe depression.

II. Evaluation of Statutory Factors for Classification as an Anabolic Steroid

DEA is proposing by this NPRM to classify boldione, desoxyxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione as anabolic steroids under the definition set forth under 21 U.S.C. 802(41)(A). As noted previously, a drug or hormone substance is defined 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 a 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 of the substances compared the chemical structure of the steroid to that of testosterone, as substances with a structure similar to that of testosterone are predicted to possess comparable pharmacological and biological activity.

Boldione is also known by the following chemical name: androsta-1,4-diene-3,17-dione. DEA has determined that the chemical structure of boldione is chemically related to that of testosterone. The chemical structure of boldione differs from testosterone by only the following two chemical groups: A ketone group at carbon 17 and a double bond between the first and second carbon. The human body would be expected to metabolize the ketone group at carbon 17 into a hydroxyl group that is present on testosterone. Furthermore, the scientific literature reports that the additional double bond at carbon 1 in boldione does not significantly decrease the anabolic activity of the substance (Vida, 1969).

Boldione is an anabolic steroid precursor, being metabolized by the body into boldenone (Galletti and Gardi, 1971), which is a schedule III anabolic steroid (21 U.S.C. 801(41)(A)(vi)). Desoxyxymethyltestosterone (DMT) is also known by the following names: 17α-methyl-5a-androst-2-en-17β-ol; and madol. DEA has determined that the chemical structure of desoxyxymethyltestosterone is chemically related to testosterone. The chemical structure of desoxyxymethyltestosterone differs from testosterone by the following four chemical features: The lack of a ketone group at the third carbon, a double bond between the second and third carbon, the lack of a double bond between the fourth and fifth carbon, and a methyl group at carbon 17. Each of these four chemical features is known through the scientific literature not to eliminate the anabolic activity of the substance (Vida, 1969).

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 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, testicular atrophy assay, gonadotropin suppression 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 examining the effects of a steroid as compared to testosterone is to perform the ventral prostate assay, seminal vesicles assay, and levator ani assay. Certain male accessory organs (i.e., the ventral prostate, seminal vesicles, and levator ani muscle) specifically need 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 Shipndonf. 1941). Numerous scientific studies have demonstrated the ability of exogenous testosterone 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; Kinc and Dorfman, 1964; Nelson et al., 1940; Scow, 1952; Wainman and Shipndonf, 1941). Thus, a steroid with testosterone-like activity will also prevent the atrophy of these three testosterone-dependent organs in castrated rats.
Testicular Atrophy Assay: Administering testosterone to non-castrated rats causes a decrease in serum levels of gonadotropins (i.e., luteinizing hormone (LH) and follicle stimulating hormone (FSH)) from normal levels. Gonadotropins are pituitary hormones that affect the size and function of the testes. The suppression of these gonadotropins by excess testosterone results in a significant decrease in the size and weight of the testes (Boris et al., 1970; McEuen et al., 1937; Moore and Price, 1938). Accordingly, a steroid with testosterone-like activity will also significantly diminish the size and weight of the testes.

Gonadotropin Suppression Assay: The castration of rats causes a substantial increase in the serum levels of gonadotropins (i.e., LH and FSH) above normal levels due to the removal of the principal source of endogenous testosterone (Gay and Bogdanove, 1969; Swerdloff et al., 1972, 1973; Swerdloff and Walsh, 1973). The administration of testosterone to castrated animals suppresses this increase in the serum levels of gonadotropins (Gay and Bogdanove, 1969; Swerdloff et al., 1972; Swerdloff and Walsh, 1973; Verjans et al., 1974). The administration of anabolic steroids with testosterone-like activity will also prevent this increase in serum levels of LH and FSH.

Androgen Receptor Binding and Efficacy Assay: Androgen receptor binding and efficacy assays are also used to demonstrate that the activity of a steroid is similar to that of testosterone. Testosterone produces its anabolic effects subsequent to binding to and activating the androgen receptor. Different cell-based assays can compare candidate steroids to testosterone for their ability to bind to and activate androgen receptors.

There are several different types of assays used to establish androgen receptor binding and efficacy. In one assay, C3H10T1/2 stem cells express androgen receptors and are used to assess steroids for their ability to bind and activate the androgen receptor (Jaynya et al., 2005a,b; Singh et al., 2003). In these stem cells, the translocation of the androgen receptor to the nucleus of the cell in the presence of the ligand (e.g., testosterone or its active metabolite dihydrotestosterone) confirms that the ligand bound to the androgen receptor and activated the downstream signaling cascade. When activated, the C3H10T1/2 stem cells differentiate into skeletal muscle cells as demonstrated by the increase in the expression of muscle specific proteins (i.e., myogenic determination transcription factor [MyoD] and myosin heavy chain [MHC]). Another assay uses human breast cancer cells genetically altered to contain a specific reporter gene (e.g., luciferase gene) regulated by androgen receptor activation (Hartig et al., 2002; Wilson et al., 2002). The expression of a bioluminescent protein (e.g., luciferase) signals both androgen receptor binding and activation.

Results of the Androgenic and Anabolic Activity Assays

In January 2006, DEA reviewed the published scientific literature for pharmacological data on the anabolic and androgenic activity of boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione using the assays described above. As discussed further below, there was sufficient information on the pharmacology of desoxymethyltestosterone to establish that desoxymethyltestosterone is pharmacologically related to testosterone (i.e., produces biological effects similar to those of testosterone). However, the published literature contained insufficient pharmacological data to determine whether boldione and 19-nor-4,9(10)-androstadienedione were pharmacologically related to testosterone. Consequently, as discussed further below, DEA sponsored pharmacological studies involving several different anabolic and androgenic activity assays to generate the data necessary to make this determination.

Androgenic and anabolic activity assay results indicate that boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione have similar pharmacological activity as testosterone.

Boldione

DEA sponsored a study 1 by the Veteran’s Administration Puget Sound Health Care System to determine the anabolic and androgenic effects of boldione in intact and castrated rats (Matsumoto and Mark, 2006). The results of these studies were compared to the results of a study by the same laboratory using a similar protocol to characterize the androgenic and anabolic effects of testosterone (Mark et al., 2003). Boldione administered to castrated male rats by silastic capsules implanted under the skin prevented the atrophy of the ventral prostate, seminal vesicle, and levator ani, and the rise in serum gonadotropins (LH and FSH) associated with castration. Boldione administration also produced testicular atrophy in intact rats. Another DEA sponsored study 2 at a laboratory at Boston University examined the ability of boldione to bind to the androgen receptor and to cause the differentiation of C3H10T1/2 stem cells into muscle cells (Bhasin, 2005). All of these effects caused by boldione in C3H10T1/2 stem cells were comparable to those of testosterone as established in experiments using the same or similar methodology (Singh et al., 2003). Collectively, the evidence indicates that the pharmacology of boldione is similar to testosterone.

Desoxymethyltestosterone

Desoxymethyltestosterone was administered subcutaneously, orally, or intramuscularly to castrated rats (Dorfan and Kincl, 1963; Kincl and Dorfan, 1964; Nutting et al., 1970). By all three routes of administration, desoxymethyltestosterone prevented the atrophy of the ventral prostate, seminal vesicle, and levator ani. Desoxymethyltestosterone also induced the expression of the bioluminescent protein luciferase in CAMA−1 breast cancer cells signaling androgen receptor binding and activation (Ayotte et al., 2006). Collectively, the evidence indicates that the pharmacology of desoxymethyltestosterone is similar to testosterone.

19-Nor-4,9(10)-Androstadienedione

DEA sponsored a study 3 by the Veteran’s Administration Puget Sound Health Care System to determine the anabolic and androgenic effects of 19-nor-4,9(10)-androstadienedione in intact and castrated rats (Matsumoto and Mark, 2006). The results of these studies were compared to the results of a study by the same laboratory using a similar protocol to characterize the anabolic and androgenic effects of testosterone (Mark et al., 2003). 19-nor-4,9(10)-androstadienedione administered to castrated male rats by silastic capsules implanted under the skin prevented the atrophy of the ventral prostate, seminal vesicle, levator ani, and the rise in serum gonadotropins (LH and FSH) associated castration. Another DEA sponsored study at a laboratory at Boston University 4

1 The study by the Veteran’s Administration Puget Sound Health Care System may be found at www.regulations.gov.
2 The study by Boston University may be found at www.regulations.gov.
3 The study by the Veteran’s Administration Puget Sound Health Care System may be found at www.regulations.gov.
4 The study by Boston University may be found at www.regulations.gov.
examined the ability of 19-nor-4,9(10)-androstadienedione to bind to the androgen receptor and to cause the differentiation of C3H10T1/2 stem cells into muscle cells (Bhasin, 2005). All of these effects caused by 19-nor-4,9(10)-androstadienedione in C3H10T1/2 stem cells were comparable to those of testosterone as established in experiments using the same or similar methodology (Singh et al., 2003). Collectively, the evidence indicates that the pharmacology of 19-nor-4,9(10)-androstadienedione is similar to testosterone.

C. Not Estrogens, Progestins, and Corticosteroids

DEA has determined that boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione are unrelated to estrogens, progestins, and corticosteroids because the chemical structure can be related to its pharmacological and biological activity. DEA found that the three substances lacked the necessary chemical structures to impart significant estrogenic activity (e.g., aromatic A ring) (Duxia et al., 1988; Jordan et al., 1985; Williams and Stancel, 1996), progesterational 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).

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)). Boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione are not dehydroepiandrosterone and are therefore not exempted from control on this basis.

III. Conclusion

Therefore, based on the above, DEA concludes that boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione 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 three substances.

IV. Impact of Proposed Rule

Effect of Classifying These Substances as Anabolic Steroids

If this rulemaking is finalized as proposed, DEA will classify boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione as schedule III anabolic steroids. If classified as schedule III anabolic steroids, any person who manufactures, distributes, dispenses, imports, or exports boldione, desoxymethyltestosterone, or 19-nor-4,9(10)-androstadienedione, who engages in research or conducts instructional activities with respect to these substances would be required to obtain a schedule III registration in accordance with the CSA and its implementing regulations. Manufacturers and importers of these three 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 three 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 three substances. Until a manufacturer applies to the Food and Drug Administration 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 boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione, except by DEA registrants, would become a violation of the CSA that may result in imprisonment and fines (21 U.S.C. 841 and 960). Possession of these three steroids, unless legally obtained, would also become subject to criminal penalties (21 U.S.C. 844).

In addition, under the CSA, these three substances would be required to comply with requirements pertaining to controlled substances in schedule III. DEA registrants are required to keep records and who possesses any quantity of any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who possesses any substance defined as an anabolic steroid is required to keep an inventory of all stocks of the substances on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11.
steroid shall 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 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 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.

Importation and Exportation. All importation and exportation of any substance defined as an anabolic steroid would be required to be in compliance with 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 is 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. 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 certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been developed in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). DEA is not able to determine whether this regulation will, if promulgated as a Final Rule, not have a significant economic impact on a substantial number of small entities. As of August 2007, DEA identified 22 dietary supplements promoted for building muscle and increasing strength that are purported to contain boldione, desoxymethyltestosterone, or 19-nor-4,9(10)-androstadienedione. Four dietary supplements purport to contain boldione; nine dietary supplements purport to contain desoxymethyltestosterone; and nine dietary supplements purport to contain 19-nor-4,9(10)-androstadienedione. All 22 dietary supplements are marketed and sold on the Internet.

The manufacturers and distributors of the 22 identified dietary supplements purported to contain boldione, desoxymethyltestosterone, or 19-nor-4,9(10)-androstadienedione 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, however, DEA is not able to determine the economic impact of the removal of these dietary supplements alone on the business of the firms. DEA has not been able to identify any chemical manufacturers that are currently using these substances as intermediates in their manufacturing process(es). 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 August 2007, DEA identified 20 chemical manufacturers and distributors that sell at least one of the three substances addressed in this NPRM. Most of the companies are located in China and sell a variety of 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. Further, DEA has no information regarding the percentage of revenue these substances constitute for each handler.

DEA has identified one company based in the U.S. that is a DEA registrant that manufactures and distributes at least one of these substances as reference products for testing laboratories. DEA notes, upon placement into schedule III, these substances may be used for analytical purposes. This company is registered with DEA and is already in compliance with the CSA and DEA implementing regulations regarding the handling of schedule III substances.

Executive Order 12866

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.

Paperwork Reduction Act

This rule proposes to regulate three 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

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 2006 was $6 million. These three substances would be a subset of those imports. The value of anabolic steroid imports for the first six months of 2007 declined by 35 percent although the quantity imported increased. The total market for these products containing these substances, therefore, is probably quite small. Moreover, DEA believes that the importation of these three 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 three substances except for legitimate research or industrial uses.

Executive Order 12998

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.

Paperwork Reduction Act

This rule proposes to regulate three 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). Therefore, DEA is specifically seeking input from the chemical industry on any manufacturing process(es) that maybe impacted by this rulemaking. Thus, DEA does not expect this proposal to impose any additional paperwork burden on the regulated industry.

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 $120,000,000 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.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

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, 871(b), 951, 958(b).

2. Section 1300.01 is amended in paragraph (b)(4) by:

A. Redesignating paragraphs (b)(4)(xii) through (b)(4)(ix) as (b)(4)(xvii) through (b)(4)(xv);

B. Adding a new paragraph (b)(4)(xvii);

C. Redesignating new paragraphs (b)(4)(xviii) through (b)(4)(xlix) as (b)(4)(xviii) through (b)(4)(xlix);

D. Adding new paragraph (b)(4)(xlix);

E. Redesignating new paragraphs (b)(4)(xli) through (b)(4)(xlii)

F. Adding new paragraph (b)(4)(xlvi) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b)(4) * * *

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

* * * * *

(xvii) desoxymethyltestosterone (17a-methyl-5a-androst-2-en-17-ol) [a.k.a., madol]

* * * * *

(xlvii) 19-nor-4,9(10)androstanedienedione (estra-4,9(10)-diene-3,17-diene)

* * * * *


Michele M. Leonhart,
Deputy Administrator.

List of References


DEPARTMENT OF THE TREASURY
Internal Revenue Service

26 CFR Part 1

[REG—104946—07]

RIN 1545—BG36

Hybrid Retirement Plans; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to a notice of proposed rulemaking (REG—104946—07) that was published in the Federal Register on Friday, December 28, 2007 (72 FR 73680) providing guidance relating to sections 411(a)(13) and 411(b)(5) of the Internal Revenue Code concerning certain hybrid defined benefit plans.

FOR FURTHER INFORMATION CONTACT: Lauzon C. Green or Linda S. F. Marshall at (202) 622–6090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 411 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG—104946—07) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG—104946—07), which was the subject of FR Doc. E7–25025, is corrected as follows:

1. On page 73683, column 3, the language “reasonably expected to result in a larger” is corrected to read “reasonably expected to result in a smaller”.

2. On page 73685, column 1, third paragraph of the column, line 8, the language “‘capital’ rule of section 411(b)(5)(b)(ii)” is corrected to read “‘capital’ rule of section 411(b)(5)(b)(ii)”.

3. On page 73689, column 2, line 3 from the bottom of the fifth paragraph of the column, the language “section 411(d)(6) relief is available for” is corrected to read “section 411(d)(6) relief is available for the”.

PART 1—[CORRECTED]

§ 1.411(a)(13)–1 [Corrected]

4. On page 73691, column 1, § 1.411(a)(13)–1(d)(3)(ii), line 18, the language “larger annual benefit at normal” is corrected to read “smaller annual benefit at normal”.

5. On page 73691, column 2, § 1.411(a)(13)–1(d)(3)(iii)(B), line 9, the language “reasonably expected to result in a larger” is corrected to read “reasonably expected to result in a smaller”.

§ 1.411(b)(5)–1 [Corrected]

6. On page 73693, column 3, § 1.411(b)(5)–1(c)(3)(iii)(A), line 17, the language “participant under the lump sum-based” is corrected to read “participant under the lump sum-based benefit”.

7. On page 73695, column 1, § 1.411(b)(5)–1(c)(5) Example 1. (iii), line 17, the language “permitted to elect (with spousal consent)” is corrected to read “permitted to elect (with spousal consent if applicable)”.

8. On page 73695, column 2, § 1.411(b)(5)–1(c)(5) Example 2. (iii), line 5, the language “‘capital’ payment in the same generalized” is corrected to read “‘capital’ if applicable” payment in the same generalized”.

9. On page 73695, column 3, § 1.411(b)(5)–1(c)(5) Example 2. (v), line 12, the language “of 5.5 percent” is corrected to read “of 5.5 percent”.

LaNita Van Dyke,
Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

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DEPARTMENT OF THE TREASURY
Internal Revenue Service

26 CFR Part 20

[REG—112196—07]

RIN 1545—BH64

Gross Estate; Election to Value on Alternate Valuation Date

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance relating to the availability of the election to use the alternate valuation method under section 2032 of