

TABLE 1.—Continued

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075	NADA 136–369, Custom Ban Wormer 9.6 (pyrantel tartrate)	558.485 (001800)
Stockton Hay & Grain Co.	NADA 49–462, Rainbrook Broiler Premix No. 1 (ampolium, arsanilic acid, ethopabate, penicillin G procaine, streptomycin) NADA 91–646, Rainbow Broiler Base Concentrate (ampolium, bacitracin zinc, ethopabate) NADA 91–647, Rainbow Broiler Base Concentrate (ampolium, chlor-tetracycline, ethopabate)	n/a (036541) n/a (036541) n/a (036541)
Triple “F”, Inc., 10104 Douglas Ave., Des Moines, IA 50322	NADA 131–146, FLAVOMYCIN 0.4 (bambermycins)	558.95 (011490)

Following the withdrawal of approval of these NADAs, Kerber Milling Co., M & M Livestock Products Co., Nutra-Blend Corp., and South St. Paul Feeds, Inc., are no longer sponsors of an approved application. Therefore, we are removing entries for these four sponsors from 21 CFR 510.600(c).

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

##### § 510.600 [Amended]

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for “Kerber Milling Co.,” “M & M Livestock Products Co.,” “Nutra-Blend Corp.,” and “South St. Paul Feeds, Inc.”; and in the table in

paragraph (c)(2) by removing the entries for “001800”, “026282”, “029341”, and “050568”.

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

##### § 558.95 [Amended]

■ 4. Section 558.95 is amended by removing and reserving paragraph (a)(3).

##### § 558.274 [Amended]

■ 5. Section 558.274 is amended in paragraph (a)(4) by removing “, 043733, and 050639” and by adding in its place “and 043733”; and in the table in paragraphs (c)(1)(i) and (c)(1)(ii) in the “Sponsor” column by removing “, 050639”.

##### § 558.485 [Amended]

■ 6. Section 558.485 is amended by removing and reserving paragraphs (b)(2) and (b)(4); and in paragraph (b)(3) by removing “, 049685, 050568, 050639, and 051359” and by adding in its place “and 049685”.

##### § 558.625 [Amended]

■ 7. Section 558.625 is amended by removing and reserving paragraphs (b)(22), (b)(31), (b)(52), and (b)(79).

##### § 558.630 [Amended]

■ 8. Section 558.630 is amended in paragraph (b)(10) by removing “, 050568, 050639”.

Dated: December 7, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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#### DEPARTMENT OF JUSTICE

##### Drug Enforcement Administration

#### 21 CFR Parts 1300 and 1308

[Docket No. DEA–264]

RIN 1117–AA95

#### Implementation of the Anabolic Steroid Control Act of 2004

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

**ACTION:** Final rule.

**SUMMARY:** The purpose of this rulemaking is to conform the Drug Enforcement Administration’s (DEA) regulations to the provisions of the Anabolic Steroid Control Act of 2004. Effective January 20, 2005, the Act amended the Controlled Substances Act (CSA) and replaced the existing definition of “anabolic steroid” with a new definition. This new definition altered the basis for all future administrative scheduling actions relating to the control of anabolic steroids as Schedule III controlled substances by eliminating the requirement to prove muscle growth. Additionally, the Act lists 59 specific substances as being anabolic steroids. As such, these substances and their salts, esters and ethers are Schedule III controlled substances. This rulemaking amends 21 CFR Parts 1300 and 1308 to reflect these changes.

The Act also amends the CSA by revising the language requiring exclusion of certain over the counter products from regulation as controlled substances. The Act clarifies that the exclusionary language in 21 U.S.C. 811(g)(1) pertains only to non-narcotic “drugs” that may, under the Federal Food, Drug, and Cosmetic Act (FDCA),

be lawfully sold over the counter without a prescription.

The statute is self-implementing with the changes that became effective on January 20, 2005. DEA has no authority to revise the changes and is simply modifying its regulations to conform to the statute. Consequently, public comments are not being solicited since they could not alter this rule.

**DATES:** The rule is effective January 17, 2006.

**FOR FURTHER INFORMATION CONTACT:**

Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307-7183.

**SUPPLEMENTARY INFORMATION:**

**DEA's Legal Authority**

DEA is the primary agency responsible for implementing the provisions of the federal Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801-971) (CSA). DEA publishes the implementing regulations for the CSA in Title 21 of the Code of Federal Regulations (CFR), §§ 1300.01 to 1316.99. The statutory scheme is designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and deter the diversion of controlled substances for illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable CSA requirements for the activity.

Drugs controlled under the CSA include opiates, hallucinogens and central nervous system stimulants and depressants. In addition, as a result of the passage of the Anabolic Steroid Control Act of 1990, anabolic steroids, as a class of drugs, were placed under the CSA effective February 27, 1991.

On October 22, 2004, the President signed into law the Anabolic Steroid Control Act of 2004, Public Law 108-358 (118 Stat. 1661). Section 2(a) amended the Controlled Substances Act (21 U.S.C. 802) by replacing the existing definition of "anabolic steroid" with a new definition for use in the future to administratively classify new steroids as Schedule III anabolic steroids. In addition, the Act listed 59 specific substances as being Schedule III

anabolic steroids. Ethers of these listed steroids were also, for the first time, controlled in Schedule III, while the isomers of these steroids were removed from Schedule III controls. Additionally, section 2(b) amended the Controlled Substances Act (21 U.S.C. 811(g)) by revising the language excluding certain over the counter products from regulation as controlled substances. The statute is self-implementing with changes that became effective January 20, 2005.

DEA is promulgating this rule as a final rule rather than a proposed rule because the changes are being made to correspond to statutory revisions. DEA has no authority to revise the changes and is simply amending its regulations to conform to the statute. Since DEA could not revise the rule based on public comments, DEA finds that notice and opportunity for public comment are unnecessary under the Administrative Procedure Act, 5 U.S.C. 553(b)(B).

**Congressional Action**

Congress enacted the Anabolic Steroid Control Act of 2004, Public Law 108-358 (118 Stat. 1661), which the President signed on October 22, 2004. The House Report (108-461) stated that the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students." The House Report also noted that steroid precursors "are as dangerous to the body as those banned under the original Act."

The Act does two things of relevance to this rulemaking. It replaces the existing definition of "anabolic steroid" in 21 U.S.C. 802 and revises the language exempting certain over the counter products from regulation as controlled substances. The changes to the definition include the following:

- Elimination of the need to prove that a steroid promotes muscle growth in order to administratively place the steroid into Schedule III of the CSA.
- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters or ethers promote muscle growth.

- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.

- Addition of dehydroepiandrosterone (DHEA) to the list of excluded substances.

**Changes to Exclusionary Language of 21 U.S.C. 811(g)**

In addition to revising the definition of anabolic steroid, the Act also amends the CSA by revising the language requiring exclusion of certain over the counter products from regulation as controlled substances. The Act clarifies that the exclusionary language in 21 U.S.C. 811 (g)(1) pertains only to nonnarcotic "drugs" that may, under the Federal Food, Drug, and Cosmetic Act (FDCA), be lawfully sold over the counter without a prescription.

Congress modified 21 U.S.C. 811(g) by changing the language in paragraphs (1) and (3). Paragraph (g)(1) previously read:

The Attorney General shall by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*], be lawfully sold over the counter without a prescription.

The revised paragraph reads:

The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of titles II and III of the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C. 802 *et seq.*) if such drug may, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*], be lawfully sold over the counter without a prescription.

The change from "substance" to "drug" clarifies that only those over the counter (OTC) non-narcotic products containing controlled substances that are regulated as drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) will be excluded from CSA regulatory requirements. Many of these steroids have previously been marketed as dietary supplements. Such dietary supplements (which are subject to requirements implemented pursuant to the Dietary Supplement Health and Education Act of 1994) are subject to different regulatory requirements than OTC non-prescription drugs under FDCA provisions.

This statutory change serves to clarify this distinction. The exclusion provided under 21 U.S.C. 811(g)(1) pertains only to nonnarcotic "drugs" that may, under the FDCA, be lawfully sold over the counter without a prescription.

The second revision to paragraph (g) specifies that the Attorney General may exclude by regulation, any compound, mixture, or preparation containing an

anabolic steroid and which is intended for administration to a human being or animal, if the Secretary of Health and Human Services recommends the exemption because its concentration, preparation, formulation, or delivery system means it does not present any significant potential for abuse. DEA has already incorporated this provision in its regulations (21 CFR 1308.33). In contrast, DEA can, without seeking a recommendation from the Secretary of Health and Human Services, exempt any chemical preparation or mixture containing a controlled substance which is not intended for human or veterinary use and which is determined not to have a significant abuse potential because of its concentration, preparation or formulation. This latter provision is incorporated into 21 CFR 1308.23.

#### Impact of the Changes

The impact of the revisions is to make all of the listed steroids and any of their salts, esters, or ethers, Schedule III controlled substances and subject to CSA requirements. Any person who manufactures, distributes, dispenses, imports or exports a substance defined as an anabolic steroid or who engages in research or conducts instructional activities with respect to substances defined as anabolic steroids must obtain a Schedule III registration in accordance with the CSA and its implementing regulations. Manufacturers and importers of the listed steroids must register with DEA and are permitted to distribute the steroids only to other DEA registrants. Only persons registered as dispensers are allowed to dispense the steroids to end users. Registered dispensers, however, are limited to practitioners, who are defined in the CSA as physicians, dentists, veterinarians, scientific investigators, pharmacies, hospitals, or other persons licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which they practice or conduct 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).

As of January 20, 2005, manufacture, import, export, distribution, or sale of the listed steroids 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).

In addition, under the CSA, a nonnarcotic Schedule III substance may be imported only if it is imported 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 Schedule III steroids will be illegal unless the person importing the steroids is registered with DEA as an importer or researcher and files the required declaration for each shipment. An individual who purchases these substances directly from foreign companies and has them shipped to the U.S. is considered to be importing even if the steroids are intended for personal use. 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).

#### Requirements for Handling Substances Defined as Anabolic Steroids

Effective January 20, 2005, those substances defined as anabolic steroids became subject to CSA regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule III controlled substance, including the following:

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

**Security.** Substances defined as anabolic steroids are subject to Schedule III-V security requirements and must 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 which are distributed on or after January 17, 2006, shall 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 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 desires registration in Schedule III for any substance defined as an anabolic steroid shall conduct an inventory of all stocks of the substances on hand at time of registration.

**Records.** All registrants are 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 compounds or for products containing these Schedule III compounds 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 compounds, if authorized for refilling, would be limited to five refills.

**Importation and Exportation.** All importation and exportation of any substance defined as an anabolic steroid must 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 occurring on or after January 20, 2005, is unlawful.

#### 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 <http://www.deadiversion.usdoj.gov>.

#### Required Certifications

##### Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 section 1(b). DEA has determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget. DEA does not have any discretion in the implementation of the Anabolic Steroid Control Act of 2004, and this rule merely codifies those statutory changes.

DEA did, however, analyze the economic impacts of the changes in recognition of the market that exists for these products. DEA was not able to determine the size of the market for these substances with any degree of certainty. The National Nutritional Foods Association indicates that the nutritional supplement market in 2003 had sales of \$19.8 billion. The sports nutrition part of the market had sales of

\$2 billion. Steroid precursors make up some fraction of the sports nutrition market. DEA believes that most steroids sold in dietary supplements in the U.S. are imported in bulk, primarily from China. According to U.S. International Trade Commission data, in the first nine months of 2004, China was the source of 3,900 kilograms of the 4,145 kg of the anabolic agents and androgens imported. The import value of the Chinese product is about \$0.27 per gram. The price per gram for pure steroid products, as listed on Internet sites, ranges from \$1.39 to \$73 (omitting Methyl D, which sells for \$150 to more than \$500/gram). Most pure products sell for between \$2.50 per gram and \$32.00/gram. Extrapolating the Chinese imports to a full year and applying the per gram markup, DEA estimates the steroid retail market to range from \$13 million to \$166 million. Because most steroids have per gram prices of less than \$8, DEA estimates that the market is probably in the middle of the range.

DEA also looked at the firms that market steroid containing supplement products. Based on Internet searches, DEA identified 64 firms that sell these products under their brand name. Besides the marketers' websites, the products were available from more than 150 Internet sites that cater to the body building and nutritional supplement market. These products may also be available from some retail store outlets and gyms.

The 64 firms identified as marketing the products under their brand name represent a variety of sectors. DEA was able to locate some industrial sector and financial information for 45 of the firms. Of those whose business category was available, five categorize themselves as food processors who manufacture dry condensed and evaporated dairy products (NAICS 311514) (whey products are widely sold as high protein supplements). Five classified themselves as manufacturers of pharmaceuticals (NAICS 325412) or botanicals (NAICS 325411). Seventeen listed themselves as drug (NAICS 424210) or food wholesalers (NAICS 424490). Twelve listed themselves as store retailers (NAICS 446191, 445299), and two as mail order houses (NAICS 454113). The others for which information was available categorized themselves as a book publisher, a research lab, a radio station, and a doctor's office. There were 19 firms for whom DEA could find no information in U.S. business databases; one of these is British. Of the 18 remaining, DEA was unable to locate any information (web site, address, phone number) on four firms whose products are being sold.

Two others had web sites, but no location information, and three had web sites and telephone numbers, but no addresses.

All of the firms identified are small entities under the Small Business Administration standards. Only two of the firms reported revenues above \$20 million; one of these filed for Chapter 11 protection in 2003 and has since sold all of its assets. Only three firms had revenues between \$10 million and \$20 million; all of these listed themselves as drug wholesalers. The 16 firms with revenues between \$1 million and \$10 million were also mainly wholesalers or manufacturers. Eighteen firms reported revenues of \$100,000 to \$1 million. Four reported revenues of less than \$100,000. Of the firms for which data were found, the majority had fewer than ten employees. It is likely that the firms for which data were not available are very small. Given the size of the firms, it is also likely that these firms are, at most, repackaging or relabeling products manufactured elsewhere.

DEA was not able to identify any firm that appeared to market only the steroid precursors although they may be the main product line for a few firms. Removing these products from the market will undoubtedly have a negative effect on many of the firms. Similarly, the 160 Internet sites identified as selling these products offer a variety of other nutritional products; some also sell sporting equipment, clothing, books, and videos. Because there is no legal substitute that produces the effects claimed for these products, it is likely that both the producers and the Internet sites will experience a loss of revenue. Without information on the percentage of revenues derived from the product lines, DEA is not able to determine whether the removal of these products alone will result in the closure of any of the firms.

#### *Regulatory Flexibility Act/Small Business Regulatory Enforcement Fairness Act of 1996*

The Regulatory Flexibility Act (5 U.S.C. 605(b)), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, applies only to regulations subject to notice and comment. Because DEA is simply promulgating a final rule to conform to statutory provisions, the Regulatory Flexibility Act does not apply to this action.

#### *Administrative Procedure Act*

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act, including notice of proposed

rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest (5 U.S.C. 553). The provisions of the Anabolic Steroid Control Act of 2004, Public Law 108-358, are self-implementing. DEA has no discretion in this matter. The changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. Hence, DEA finds it unnecessary to publish for public notice and comment.

#### *Executive Order 12988*

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

#### *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.

#### *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 \$115,000,000 or more 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.

#### **List of Subjects**

##### *21 CFR Part 1300*

Chemicals; Drug traffic control.

##### *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 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, 871(b), 951, 958(f).

■ 2. In § 1300.01(b), paragraph (4) is revised to read as follows:

#### **§ 1300.01 Definitions relating to controlled substances.**

\* \* \* \* \*

(b) \* \* \*

(4) The term anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes:

- (i) 3 $\beta$ ,17-dihydroxy-5 $\alpha$ -androstane
- (ii) 3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (iii) 5 $\alpha$ -androstan-3,17-dione
- (iv) 1-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene)
- (v) 1-androstenediol (3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene)
- (vi) 4-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-4-ene)
- (vii) 5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-5-ene)
- (viii) 1-androstenedione ([5 $\alpha$ ]-androst-1-en-3,17-dione)
- (ix) 4-androstenedione (androst-4-en-3,17-dione)
- (x) 5-androstenedione (androst-5-en-3,17-dione)
- (xi) bolasterone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (xii) boldenone (17 $\beta$ -hydroxyandrost-1,4-diene-3-one)
- (xiii) calusterone (7 $\beta$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (xiv) clostebol (4-chloro-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (xv) dehydrochloromethyltestosterone (4-chloro-17 $\beta$ -hydroxy-17 $\alpha$ -methyl-androst-1,4-dien-3-one)
- (xvi)  $\Delta$ 1-dihydrotestosterone (a.k.a. '1-testosterone') (17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one)
- (xvii) 4-dihydrotestosterone (17 $\beta$ -hydroxy-androstan-3-one)
- (xviii) drostanolone (17 $\beta$ -hydroxy-2 $\alpha$ -methyl-5 $\alpha$ -androstan-3-one)
- (xix) ethylestrenol (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-4-ene)
- (xx) fluoxymesterone (9-fluoro-17 $\alpha$ -methyl-11 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-en-3-one)
- (xxi) formebolone (2-formyl-17 $\alpha$ -methyl-11 $\alpha$ ,17 $\beta$ -dihydroxyandrost-1,4-dien-3-one)
- (xxii) furazabol (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrostano[2,3-c]-furazan)
- (xxiii) 13 $\beta$ -ethyl-17 $\alpha$ -hydroxygon-4-en-3-one
- (xxiv) 4-hydroxytestosterone (4,17 $\beta$ -dihydroxy-androst-4-en-3-one)
- (xxv) 4-hydroxy-19-nortestosterone (4,17 $\beta$ -dihydroxy-estr-4-en-3-one)
- (xxvi) mestanolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androstan-3-one)
- (xxvii) mesterolone (1 $\alpha$ -methyl-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-one)
- (xxviii) methandienone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrost-1,4-dien-3-one)
- (xxix) methandriol (17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-5-ene)
- (xxx) methenolone (1-methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one)

- (xxxvi) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (xxxvii) 17 $\alpha$ -methyl-3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (xxxviii) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-ene
- (xxxix) 17 $\alpha$ -methyl-4-hydroxynandrolone (17 $\alpha$ -methyl-4-hydroxy-17 $\beta$ -hydroxyestr-4-en-3-one)
- (xl) methyldienolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestra-4,9(10)-dien-3-one)
- (xli) methyltrienolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestra-4,9-11-trien-3-one)
- (xlii) methyltestosterone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (xliiii) mibolerone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (xliv) 17 $\alpha$ -methyl- $\Delta$ 1-dihydrotestosterone (17 $\beta$ -hydroxy-17 $\alpha$ -methyl-5 $\alpha$ -androst-1-en-3-one) (a.k.a. '17 $\alpha$ -methyl-1-testosterone')
- (xlv) nandrolone (17 $\beta$ -hydroxyestr-4-en-3-one)
- (xlvi) 19-nor-4-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxyestr-4-ene)
- (xlvii) 19-nor-4-androstenediol (3 $\alpha$ ,17 $\beta$ -dihydroxyestr-4-ene)
- (xlviii) 19-nor-5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxyestr-5-ene)
- (xlix) 19-nor-5-androstenediol (3 $\alpha$ ,17 $\beta$ -dihydroxyestr-5-ene)
- (l) 19-nor-4-androstenedione (estr-4-en-3,17-dione)
- (li) 19-nor-5-androstenedione (estr-5-en-3,17-dione)
- (lii) norbolethone (13 $\beta$ ,17 $\alpha$ -diethyl-17 $\beta$ -hydroxygon-4-en-3-one)
- (liiii) norclostebol (4-chloro-17 $\beta$ -hydroxyestr-4-en-3-one)
- (liv) norethandrolone (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (lv) normethandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (lvi) oxandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-2-oxa-[5 $\alpha$ ]-androstan-3-one)
- (lvii) oxymesterone (17 $\alpha$ -methyl-4,17 $\beta$ -dihydroxyandrost-4-en-3-one)
- (lviii) oxymetholone (17 $\alpha$ -methyl-2-hydroxymethylene-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-one)
- (lix) stanozolol (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androst-2-eno[3,2-c]-pyrazole)
- (lx) stenbolone (17 $\beta$ -hydroxy-2-methyl-[5 $\alpha$ ]-androst-1-en-3-one)
- (lxi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
- (lxii) testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one)
- (lxiii) tetrahydrogestrinone (13 $\beta$ ,17 $\alpha$ -diethyl-17 $\beta$ -hydroxygon-4,9,11-trien-3-one)
- (lxiv) trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-3-one)
- (lxv) Any salt, ester, or ether of a drug or substance described in this paragraph. Except 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. 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 paragraph.

\* \* \* \* \*

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 4. In § 1308.13, paragraph (f) is revised to read as follows:

### § 1308.13 Schedule III.

\* \* \* \* \*

(f) *Anabolic Steroids.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:

(1) Anabolic steroids (see § 1300.01 of this chapter)—4000

(2) [Reserved]

\* \* \* \* \*

■ 5. In § 1308.21, paragraph (a) is revised to read as follows:

### § 1308.21 Application for exclusion of a non-narcotic drug.

(a) Any person seeking to have any nonnarcotic drug that may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

\* \* \* \* \*

■ 6. In § 1308.33, paragraph (a) is revised to read as follows:

### § 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter, which is intended for administration to

a human being or animal, if, because of its concentration, preparation, formulation, or delivery system, it has no significant potential for abuse.

\* \* \* \* \*

Dated: November 23, 2005.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. 05-23907 Filed 12-15-05; 8:45 am]

BILLING CODE 4410-09-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 301

[TD 9235]

RIN 1545-BD77

#### Classification of Certain Foreign Entities

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations relating to certain business entities included on the list of foreign business entities that are always classified as corporations for Federal tax purposes.

**DATES:** *Effective Date:* These regulations are effective on December 16, 2005.

*Applicability Date:* For the dates of applicability of these regulations, see § 301.7701-2(e)(4).

**FOR FURTHER INFORMATION CONTACT:** Ronald M. Gootzeit, (202) 622-3860 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

On April 14, 2005, the IRS and Treasury Department published in the **Federal Register** temporary regulations (TD 9197, 2005-18 I.R.B. 985 [70 FR 19697]) and a notice of proposed rulemaking (REG-148521-04, 2005-18 I.R.B. 995 [70 FR 19722]) under section 7701 of the Internal Revenue Code (Code). The regulations added certain foreign business entities to the list of entities in § 301.7701-2(b)(8) (the per se corporation list) in response to the adoption by the Council of the European Union of a Council Regulation (2157/2001 2001 O.J. (L 294)) permitting a new business entity, the European public limited liability company (Societas Europaea or SE). Specifically, the temporary and proposed regulations added the SE, Estonian Aktsiaselts, Latvian Akciju Sabiedriba, Lithuanian Akcine Bendroves, Slovenian Delniska

Druzba, and Liechtenstein Aktiengesellschaft to the per se list of corporations. For further background see TD 9197 (2005-18 I.R.B. 985; 70 FR 19697) and Notice 2004-68 (2004-2 CB 706).

#### Explanation of Provisions

No substantive comments were received regarding the temporary and proposed regulations. Accordingly, these regulations finalize the proposed regulations without modification and revise the temporary regulations to cross reference to the new provisions.

#### Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative and Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the Notice of Proposed Rulemaking preceding the final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

#### Drafting Information

The principal author of these regulations is Ronald M. Gootzeit of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

#### List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and Recordkeeping requirements.

#### Amendments to the Regulations

■ Accordingly, 26 CFR part 301 is amended as follows:

#### PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 continues to read, in part, as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

■ **Par. 2.** Section 301.7701-2 is amended by:

- 1. Adding six entries in alphabetical order to paragraph (b)(8)(i).
- 2. Removing paragraph (b)(8)(vi).

■ 3. Adding paragraphs (e)(3) and (4).

The additions read as follows:

#### § 301.7701-2 Business entities; definitions.

\* \* \* \* \*

(b) \* \* \*

(8) \* \* \*

(i) \* \* \*

Estonia, Aktsiaselts

European Economic Area/European Union, Societas Europaea

\* \* \* \* \*

Latvia, Akciju Sabiedriba

\* \* \* \* \*

Liechtenstein, Aktiengesellschaft

Lithuania, Akcine Bendroves

\* \* \* \* \*

Slovenia, Delniska Druzba.

\* \* \* \* \*

(e) \* \* \*

(3) [Reserved]. For further guidance, see § 301.7701-2T(f).

(4) The reference to the Estonian, Latvian, Liechtenstein, Lithuanian, and Slovenian entities in paragraph (b)(8)(i) of this section applies to such entities formed on or after October 7, 2004, and to any such entity formed before such date from the date any person or persons, who were not owners of the entity as of October 7, 2004, own in the aggregate a 50 percent or greater interest in the entity. The reference to the European Economic Area/European Union entity in paragraph (b)(8)(i) of this section applies to such entities formed on or after October 8, 2004.

■ **Par. 3.** Section 301.7701-2T is amended by:

■ 1. Removing paragraph (b)(8)(vi).

■ 2. Revising paragraph (e)(3).

The revision reads as follows:

#### § 301.7701-2T Business entities; definitions (temporary).

\* \* \* \* \*

(e) \* \* \*

(3) [Reserved]. For further guidance, see § 301.7701-2(e)(4).

\* \* \* \* \*

Approved: December 8, 2005.

**Mark E. Matthews,**

*Deputy Commissioner for Services and Enforcement.*

**Erin Solomon,**

*Acting Deputy Assistant Secretary of the Treasury.*

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