

Note: The request should be submitted directly to the Manager, Standardization Branch, ANM-113, and a copy sent to the cognizant FAA Principal Inspector (PI). The PI will then forward comments or concurrence to the Manager, Standardization Branch, ANM-113.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Short Brothers, PLC, 2011 Crystal Drive, Suite 713, Arlington, Virginia 22202-3719. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1801 Lind Avenue SW., Renton, Washington.

This amendment becomes effective March 22, 1991.

Issued in Renton, Washington, on February 4, 1991.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-3434 Filed 2-12-91; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Anabolic Steroids

AGENCY: Drug Enforcement Administration (DEA), DOJ.

ACTION: Final rule.

SUMMARY: The DEA is amending its regulations to place anabolic steroids into Schedule III of the Controlled Substances Act, as required by the Anabolic Steroids Control Act of 1990. Such placement requires any handler of these anabolic steroids to comply with the requirements of the Controlled Substances Act.

EFFECTIVE DATE: February 27, 1991.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION: The Anabolic Steroids Control Act of 1990 (Pub. L. 101-647) requires the placement of anabolic steroids into Schedule III of the Controlled Substances Act (21 U.S.C. 801, et seq.) and provides a definition for such steroids. This placement into Schedule III, therefore, classifies these anabolic steroids as controlled substances. The Controlled Substances

Act (CSA) requires that any person who manufactures, distributes or dispenses any controlled substance, or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance, must obtain a registration with the DEA, meet certain security requirements, take an inventory of the stocks of controlled substances on hand, and maintain retrievable records for a specified period of time. Persons interested in conducting activities allowed for Schedule III substances must comply with the following:

1. *Registration.* Any person not currently registered for Schedule III activities who manufactures, distributes, dispenses, imports, exports, conducts chemical analysis, engages in research, or conducts instructional activities with respect to anabolic steroids, or who proposes to engage in such activities, shall submit an application for Schedule III registration to conduct such activities in accordance with 21 CFR parts 1301 and 1311.

2. *Disposal of stock.* Any person who elects not to obtain a Schedule III registration or is not entitled to such registration must surrender all quantities of currently held anabolic steroids in accordance with procedures outlined in 21 CFR 1307.21 on or before February 27, 1991, or may transfer all quantities of currently held anabolic steroids to a person registered under the CSA and authorized to possess Schedule III controlled substances on or before February 27, 1991. Anabolic steroids to be surrendered to DEA must be listed on a DEA Form 41, "Inventory of Controlled Substances Surrendered for Destruction." DEA Form 41 and instructions can be obtained from the nearest DEA office.

3. *Security.* Anabolic steroids must be manufactured, distributed and stored in accordance with 21 CFR 1301.71-1301.76.

4. *Labeling and packaging.* All labels and labeling for commercial containers of anabolic steroids, packaged on or after August 27, 1991, shall comply with the requirements of 21 CFR 1302.03-1302.08. Any commercial containers of anabolic steroids packaged prior to August 27, 1991 and not meeting the requirements specified in 21 CFR 1302.03-1302.05 shall not be distributed on or after November 27, 1991. In the event the effective date imposes special hardships on any "manufacturer", as defined in section 102(15) of the CSA (21 U.S.C. 802(15)), the DEA will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

5. *Inventory.* Every registrant required to keep records, who possesses any quantity of anabolic steroids, shall

maintain an inventory, pursuant to 21 CFR 1304.11-1304.19, of all stocks of anabolic steroids. Every registrant who desires registration in Schedule III or is currently registered in Schedule III shall conduct an inventory of all stocks of anabolic steroids on February 27, 1991 or on the date thereafter the registrant begins handling anabolic steroids.

6. *Records.* All registrants required to keep records pursuant to 21 CFR 1304.21-1304.27 shall maintain such records on anabolic steroids commencing on February 27, 1991.

7. *Prescriptions.* All prescriptions for products containing anabolic steroids shall comply with 21 CFR 1306.02-1306.06 and 1306.21-1306.26 commencing on February 27, 1991. All prescriptions for products containing such substances issued on or before February 27, 1991, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after August 27, 1991.

8. *Importation and exportation.* All importation and exportation of anabolic steroids shall be in compliance with 21 CFR part 1312.

9. *Criminal liability.* Any activity with respect to anabolic steroids, not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act, shall be unlawful on and after February 27, 1991 and subject to the penalties set forth in these acts. On or after February 27, 1991, any activity with respect to human growth hormones not authorized by, or in violation of, 21 U.S.C. 333(e)(1) of the Food, Drug, and Cosmetic Act is punishable by not more than five years in prison, and such fines as are authorized by title 18 U.S.C., or both. Title 21 U.S.C. 333(e)(2) provides that whoever commits an offense set forth in (e)(1) above and such offense involves an individual under 18 years of age, is guilty of an offense punishable by not more than ten years in prison, and such fines as are authorized by title 18 U.S.C., or both.

The Anabolic Steroids Control Act provides that certain anabolic steroids, those that are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration, are excluded from the definition of an anabolic steroid. In that the Secretary of Health and Human Services approves pharmaceutical products and not raw chemicals, only those approved products which are manufactured, distributed and administered as implants to nonhuman species will be excluded.

In addition, the Attorney General may exempt certain anabolic steroid products, upon the recommendation of the Secretary of Health and Human Services, if, because of their concentration, preparation, mixture or delivery system, they have no significant potential for abuse.

The DEA will be publishing regulations on how one may apply for these exclusions and exemptions and provide separate lists of these excluded veterinary implant products and exempt anabolic steroid products in a proposed Federal Register notice. Thereafter, the DEA will republish updated lists on an annual basis.

The list of anabolic steroids under 21 CFR 1308.02(b) shows certain anabolic steroids with an additional name in parenthesis. These names reflect the correct spelling for these anabolic steroids.

The Administrator of the Drug Enforcement Administration hereby certifies that this final rule will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The final rule is not a major rule for the purposes of Executive Order (E.O.) 12291 of February 17, 1981.

This scheduling action is a formal rulemaking that is required by Public Law 101-647, and as such, is exempt from the consultation requirements of E.O. 12291.

This action has been analyzed in accordance with the principles and criteria in E.O. 12612, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug Enforcement Administration, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by Public Law 100-647 and delegated to the Administrator of the DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

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

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

2. Section 1308.02 is amended by redesignating the current paragraphs (b) through (g) as paragraphs (c) through (h) and adding a new paragraph (b) to read as follows:

§ 1308.02 Definitions.

(b) The term *anabolic steroid* means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

- (1) Boldenone;
- (2) Chlorotestosterone (4-chlorotestosterone);
- (3) Clostebol;
- (4) Dehydrochloromethyltestosterone;
- (5) Dihydrotestosterone (4-dihydrotestosterone);
- (6) Drostanolone;
- (7) Ethylestrenol;
- (8) Fluoxymesterone;
- (9) Formebolone (formebolone);
- (10) Mesterolone;
- (11) Methandienone;
- (12) Methandranone;
- (13) Methandriol;
- (14) Methandrostenolone;
- (15) Methenolone;
- (16) Methyltestosterone;
- (17) Mibolerone;
- (18) Nandrolone;
- (19) Norethandrolone;
- (20) Oxandrolone;
- (21) Oxymesterone;
- (22) Oxymetholone;
- (23) Stanolone;
- (24) Stanozolol;
- (25) Testolactone;
- (26) Testosterone;
- (27) Trenbolone; and

(28) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which 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, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

3. Section 1308.13 is amended by adding a new paragraph (f) 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, isomers, and salts of isomers whenever the

existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids.....4000

Dated: February 4, 1991.

Robert C. Bonner,
Administrator, Drug Enforcement
Administration.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Miami, Florida Regulation CCGD7-91-06]

Security Zone Regulations: U.S. Coast Guard Base Miami Beach, Miami Beach, FL

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a security zone around U.S. Coast Guard Base Miami Beach, Miami Beach, Florida. This zone is needed to protect U.S. Coast Guard Base Miami Beach and the vessels moored thereto from potential subversive acts by any unknown person or persons hostile to the United States. The zone is established at a one hundred yard radius upon and under the waters of Biscayne Bay off Coast Guard Base Miami Beach, centered in approximate position latitude 25-46.25N, longitude 080-08.8W. Entry into this zone is prohibited unless authorized by the Captain of the Port, Miami, Florida, or his designated representative.

FOR FURTHER INFORMATION CONTACT: Lt. Jones, Project Officer, USCG Marine Safety Office, 155 S. Miami Ave., Miami, Florida 33130, (305) 536-5693.

EFFECTIVE DATES: This regulation becomes effective on 14 January 1991 at 4:00 p.m. local time and will remain in effect until further notice. A notice will be published in the Federal Register announcing termination of the rule.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publishing a NPRM and delaying its effective date would be contrary to national security interests since immediate action is needed to protect U.S. Coast Guard Base Miami Beach and vessels moored thereto.