Food and Drug Administration, HHS

§ 1308.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term Act means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(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) Dehydrochlormethyltestosterone;
(5) Dihydrotestosterone (4-dihydrotestosterone);
(6) Drostanolone;
(7) Ethylestrenol;
(8) Fluoxymesterone;
(9) Formebulone (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) Stanozolol;
(24) Stanolol;
(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.

(c) The term hearing means any hearing held pursuant to this part for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act.

(d) The term isomer means the optical isomer, except as used in §1308.11(d) and §1308.12(b)(4). As used in §1308.11(d), the term isomer means the optical, positional, or geometric isomer. As used in §1308.12(b)(4), the term isomer means the optical or geometric isomer.

(e) The term interested person means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act.

(f) The term narcotic drug means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) Opium, opiates, derivatives of opium and opiotes, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(2) Poppy straw and concentrate of poppy straw.

(3) Coca leaves, except coco leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(4) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(5) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(6) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (1) through (5).
§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned an “Administration Controlled Substances Code Number” for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §§ 1301.44 and 1311.43 of this chapter and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.

§ 1308.04 Submission of information by manufacturers.

(a) Each person who manufactures, packages, repackages, labels, relabels, or distributes under his own label any product (including any compound, mixture, or preparation, diagnostic, reagent, buffer, or biological) containing any quantity of any controlled substance (whether such product is itself controlled or is excepted, exempted, or excluded from some or all controls pursuant to § 1308.21-24 or § 1308.31-32) shall submit information required in paragraph (b) of this section for each such product being manufactured or sold on July 1, 1972. The information should be submitted by registered mail, return receipt requested, to the Regulatory Support Section, Attention: Project Label, Drug Enforcement Administration, Department of Justice, Washington, DC 20537, by August 31, 1972. In the case of new products manufactured after July 1, 1972, or new dosage forms or other unit forms manufactured after July 1, 1972, or changes in information submitted by August 31, 1972, the registrant shall submit information regarding such item within 30 days after the date on which the manufacture commences or information change occurs. In the case of products, the manufacture of which is discontinued after July 1, 1972, the registrant shall submit a notice of such discontinuance with his initial submission.

(b) Two labels or other documents reflecting the following information shall be submitted with reference to each dosage form or other unit form of each item containing any quantity of any controlled substance:

(1) The trade name, brand name, or other commercial name of the product;