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## Title 21 – Food and Drugs

### Chapter II – Drug Enforcement Administration, Department of Justice

#### Part 1308 – Schedules of Controlled Substances

##### Exempt Anabolic Steroid Products

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

**Source:** 38 FR 8254, Mar. 30, 1973, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

#### § 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.
- (b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.
- (c) An application for an exemption under this section shall be submitted in triplicate and contain the following information:
  - (1) The name and address of the applicant;
  - (2) The name of the product;
  - (3) The chemical structural formula or description for any anabolic steroid contained in the product;
  - (4) The complete description of dosage and quantitative composition of the dosage form;
  - (5) A description of the delivery system, if applicable;
  - (6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;
  - (7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;
  - (8) The label and labeling of the immediate container and the commercial containers, if any, of the product;
  - (9) The units in which the dosage form is ordinarily available; and
  - (10) The facts which the applicant believes justify:
    - (i) A determination that the product has no significant potential for abuse and
    - (ii) a granting of an exemption under this section.

**Exemption of certain anabolic steroid products; application.**

- (d) Within a reasonable period of time after the receipt of the application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) of this section is lacking or is not set forth so as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (c) of this section. If accepted for filing, the Administrator will request from the Secretary for Health and Human Services his recommendation, as to whether such product which contains an anabolic steroid should be considered for exemption from certain portions of the Controlled Substances Act. On receipt of the recommendation of the Secretary, the Administrator shall make a determination as to whether the evidence submitted or otherwise available sufficiently establishes that the product possesses no significant potential for abuse. The Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued, and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.
- (e) The Administrator may revoke any exemption granted pursuant to section 1903(a) of Public Law 101-647 by following the procedures set forth in paragraph (d) of this section for handling an application for an exemption which has been accepted for filing.

*[56 FR 42936, Aug. 30, 1991; 57 FR 10815, Mar. 31, 1992, as amended at 62 FR 13968, Mar. 24, 1997; 70 FR 74657, Dec. 16, 2005; 75 FR 10679, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]*