

EXEMPT ANABOLIC STEROID PRODUCTS

§ 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 Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(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.

(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 non-acceptance 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]

§ 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822-829 and 952-954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

[62 FR 13967, Mar. 24, 1997]

EXEMPT CANNABIS PLANT MATERIAL,
AND PRODUCTS MADE THEREFROM,
THAT CONTAIN
TETRAHYDROCANNABINOLS

§ 1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

(a) Any processed plant material or animal feed mixture containing any amount of tetrahydrocannabinols (THC) that is both:

(1) Made from any portion of a plant of the genus *Cannabis* excluded from the definition of marijuana under the Act [i.e., the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination] and

(2) Not used, or intended for use, for human consumption, has been exempted by the Administrator from the application of the Act and this chapter.

(b) As used in this section, the following terms shall have the meanings specified:

(1) The term *processed plant material* means cannabis plant material that

has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption.

(2) The term *animal feed mixture* means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).

(3) The term *used for human consumption* means either:

(i) Ingested orally or

(ii) Applied by any means such that THC enters the human body.

(4) The term *intended for use for human consumption* means any of the following:

(i) Designed by the manufacturer for human consumption;

(ii) Marketed for human consumption; or

(iii) Distributed, exported, or imported, with the intent that it be used for human consumption.

(c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to § 1308.23, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

[66 FR 51544, Oct. 9, 2001]

HEARINGS

§ 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative