

§ 1308.26

for an exclusion under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and have published 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 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.

(d) The Administrator may at any time revoke or modify any designation of excluded status granted pursuant to this section by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

[56 FR 42936, Aug. 30, 1991, as amended at 75 FR 10679, Mar. 9, 2010]

§ 1308.26 Excluded veterinary anabolic steroid implant products.

(a) Products containing an anabolic steroid, 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 all schedules pursuant to section

21 CFR Ch. II (4–1–11 Edition)

102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)). A listing of the excluded products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) In accordance with section 102(41)(B)(ii) of the Act (21 U.S.C. 802(41)(B)(ii)) if any person prescribes, dispenses, or distributes a product listed in paragraph (a) of this section for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of section 102(41)(A) of the Act (21 U.S.C. 802(41)(A)).

[56 FR 42936, Aug. 30, 1991, as amended at 57 FR 19534, May 7, 1992; 58 FR 15088, Mar. 19, 1993; 62 FR 13967, Mar. 24, 1997; 75 FR 10679, Mar. 9, 2010]

EXEMPTED PRESCRIPTION PRODUCTS

§ 1308.31 Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in §1308.12(e), or in §1308.13(b) or (c), or in §1308.14, or in §1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)) may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) An application for an exemption under this section shall contain the following information:

(1) The complete quantitative composition of the dosage form.

(2) Description of the unit dosage form together with complete labeling.

(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

(4) Details of synergisms and antagonisms among ingredients.