§ 1308.25 Exclusion of a veterinary anabolic steroid implant product; application.

(a) Any person seeking to have any anabolic steroid product, 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, identified as being excluded from any schedule, pursuant to section 102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)), 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 any exclusion 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) A complete description of dosage and quantitative composition of the dosage form;

(5) The conditions of use including whether or not Federal law restricts this product to use by or on the order of a licensed veterinarian;

(6) A description of the delivery system in which the dosage form will be distributed with sufficient detail to identify the product (e.g., 20 cartridge brown plastic belts);

(7) The label and labeling of the immediate container and the commercial containers, if any, of the product;

(8) The name and address of the manufacturer of the dosage form if different from that of the applicant; and

(9) Evidence that the product has been approved by the Secretary of Health and Human Services for administration through implant to cattle or other nonhuman species.

(c) Within a reasonable period of time after the receipt of an application 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.
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§ 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.
5. Deterrent effects of the noncontrolled ingredients.
6. Complete copies of all literature in support of claims.
7. Reported instances of abuse.
8. Reported and anticipated adverse effects.
9. Number of dosage units produced for the past 2 years.
10. Within a reasonable period of time after the receipt of an application for an exemption under this section,