§ 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 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)).


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. 801(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.