EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Menogen	Sage Pharmaceuticals, Shreveport, LA.	59243–570	TB	Esterified estrogens Methyltestosterone	1.25 mg. 2.5 mg.
Menogen HS	Sage Pharmaceuticals, Shreveport, LA.	59243–560	TB	Esterified estrogens Methyltestosterone	0.625 mg. 1.25 mg.
Synovex Plus, in-process, granulation.	Fort Dodge Animal Health, Fort Dodge, IA.		Drum	Trenbolone acetate Estradiol benzoate	25 parts. 3.5 parts.
Synovex Plus, in-process, bulk pellets.	Fort Dodge Animal Health, Fort Dodge, IA.		Drum	Trenbolone acetate Estradiol benzoate	25.00 mg. 3.50 mg pellet.
Testoderm, 4 mg/d	Alza Corp., Palo Alto, CA	17314–4608	Patch	Testosterone	10 mg.
Testoderm, 6 mg/d	Alza Corp., Palo Alto, CA	17314–4609	Patch	Testosterone	15 mg.
Testoderm, with Adhesive, 6 mg/d.	Alza Corp., Palo Alto, CA	17314–2836	Patch	Testosterone	15 mg.
Testoderm, in-process film.	Alza Corp., Palo Alto, CA		Sheet	Testosterone	0.25 mg/cm^2.
Testoderm, with Adhesive, in-process film.	Alza Corp., Palo Alto, CA		Sheet	Testosterone	0.25 mg/cm^2.
Tilapia Sex Reversal Feed (Investigational).	Rangen, Inc., Buhl, ID		Plastic Bags	Methyltesterone	60 mg/kg fish feed.

Interested persons are invited to submit their comments in writing in regard to this interim rule. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Acting Deputy Assistant Administrator shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments and objections filed. Thereafter, he shall reinstate, revoke, or amend his original order as he determines appropriate.

This exemption relieves persons who handle the products in the course of legitimate business from the registration, records, reports, prescription, physical security, import, and export requirements associated with Schedule III substances. Accordingly, the Acting Deputy Assistant Administrator certifies that this action will have no impact on the ability of small businesses to compete and he therefore determines that no regulatory flexibility analysis is required.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

It has been determined that drug control matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12866. Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon review by OMB. Nevertheless, the Acting Deputy Assistant Administrator has determined that this is not a ''major rule,'' as that term is used in E.O. 18866, and that it would otherwise meet the applicable standards of sections 2(a) and 2(b)(2) of E.O. 12778.

Dated: May 21, 1997.

Terrance W. Woodworth,

Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 97–14111 Filed 5–29–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 161I]

Schedules of Controlled Substances: Excluded Veterinary Anabolic Steroid Implant Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim rule and request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) is designating eight veterinary anabolic steroid implant products as being excluded from the Controlled Substances Act. This action is part of the ongoing implementation of the Anabolic Steroids Control Act.

DATES: Effective Date: May 30, 1997. Comments must be submitted on or before July 29, 1997.

ADDRESSES: Comments and objections should be submitted to the Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section. Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: The Anabolic Steroids Control Act of 1990 (ASCA) (title XIX of Pub. L. 101–647) placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.).* Section 1902(b)(41)(B)(i) of the ASCA provides for the exclusion of any anabolic steroid which the Secretary of Health and Human Services has approved for administration through implants to cattle of other nonhuman species. The procedure for implementing this section of the ASCA is described in section 1308.25 of Title 21 Code of Federal Regulations. The purpose of this rule is to identify eight products which the Acting Deputy Assistant Administrator for the Office of Diversion Control finds meet the excluded veterinary anabolic steroid implant product criteria.

The Acting Deputy Assistant Administrator, having reviewed the applications which were made in conformance with 21 CFR 1308.25, finds that the anabolic steroid products, Component™ E–H, Component™ TE–S, Component™ T–H, Component™ T–S, Revalor®-G, Revalor®-H, Synovex® H, and Synovex® Plus, are expressly intended for administration through

implants to cattle and have been approved by the Secretary of Health and Human Services for such use. Therefore, pursuant to the authority vested in the Attorney General by title XIX of Pub. L. 101–647 as delegated to the Administrator of the DEA pursuant to 21 U.S.C. 871(a) and 28 CFR 0.100, the Acting Deputy Assistant Administrator hereby orders that the following anabolic steroid veterinary implant products be added to those described in 21 CFR 1308.26(a) and excluded from application of the CSA.

EXCLUDED VETERINARY ANABOLIC STEROID IMPLANT PRODUCTS

Trade name	Company	NDC code	Delivery system	Ingredients	Quantity
Component E–H ..	VetLife, Inc., Norcross, GA	021641–002	20 implant belt ..... 8 pellets/implant	Testosterone propionate .... Estradiol benzoate	200 mg/implant. (25 mg/pellet). 20 mg/implant. (2.5 mg/pellet).
Component E–H ..	Elanco, Scarborough, Ont ..	DIN01968327	20 implant belt ..... 8 pellets/implant	Testosterone propionate .... Estradiol benzoate	200 mg/implant. (25 mg/pellet). 20 mg/implant. (2.5 mg/pellet).
Component TE–S	VetLife, Inc., Norcross, GA	021641–004	20 implant belt ..... 6 pellets/implant	Trenbolone acetate ..... Estradiol	120 mg/implant. (20 mg/pellet). 24 mg/implant. (4 mg/pellet).
Component T–H ..	VetLife, Inc., Norcross, GA	021641–006	20 implant belt ..... 10 pellets/implant	Trenbolone acetate	200 mg/implant. (20 mg/pellet).
Component T–S ..	VetLife, Inc., Norcross, GA	021641–005	20 implant belt ..... 7 pellets/implant	Trenbolone acetate	140 mg/implant. (20 mg/pellet).
Revalor-G	Hoechst Roussel Vet, Somerville, NJ.	12799–811	10 implant cartridge .. 2 pellets/implant	Trenbolone acetate ..... Estradiol	40 mg/implant. (20 mg/pellet). 4 mg/implant. (2 mg/pellet).
Revalor-H	Hoechst Roussel Vet, Somerville, NJ.	12799–810	10 implant cartridge .. 7 pellets/implant	Trenbolone acetate ..... Estradiol	140 mg/implant. (20 mg/pellet). 14 mg/implant. (2 mg/pellet).
Synovex H	Fort Dodge Labs, Fort Dodge, IA.	0856–3901	10 implant cartridge .. 8 pellets/implant	Testosterone propionate .... Estradiol benzoate	200 mg/implant. (25 mg/pellet). 20 mg/implant. (2.5 mg/pellet).
Synovex Plus	Fort Dodge Labs, Fort Dodge, IA.	0856–3904	10 implant cartridge .. 8 pellets/implant	Trenbolone acetate ..... Estradiol benzoate	200 mg/implant. (25 mg/pellet). 28 mg/implant. (3.5 mg/pellet).

The exemption of these products relates to their production, distribution, and use in animals only. If any person distributes, dispenses or otherwise diverts these products to use in humans, he/she shall be deemed to have distributed a Schedule III controlled substance and may be prosecuted for CSA violations.

Interested persons are invited to submit their comments in writing with regard to this interim rule. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Acting Deputy Assistant Administrator shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Acting Deputy Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

The granting of excluded status relieves persons who handle the excluded products in the course of legitimate business from the registration, record keeping, security, and other requirements imposed by the CSA. Accordingly, the Acting Deputy Assistant Administrator certifies that this action will have no negative economic impact upon small entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*).

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

It has been determined that drug control matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12866. Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon review by OMB. Nevertheless, the Acting Deputy Assistant Administrator has determined that this is not a ''major rule,'' as that term is used in E.O. 12866, and that it would otherwise meet the applicable standards of sections 2(a) and 2(b)(2) of E.O. 12778.

Dated: May 21, 1997.

Terrance W. Woodworth,

Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 97–14112 Filed 5–29–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906

[SPATS No. CO–034–FOR]

Colorado Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.