

EXCLUDED VETERINARY ANABOLIC STEROID IMPLANT PRODUCTS—Continued

| Trade name         | Company                              | NDC or DIN No. | Delivery system                          | Ingredients                   | Quantity                       |
|--------------------|--------------------------------------|----------------|--|-------------------------------|--------------------------------|
| Revalor-H .....    | Hoechst Roussel Vet, Somerville, NJ. | 12799-810      | 10 implant cartridge, 7 pellets/implant. | Trenbolone acetate .....      | 140 mg/implant (20 mg/pellet)  |
|                    |                                      |                |  | Estradiol .....               | 14 mg/implant (2 mg/pellet)    |
| Revalor-S .....    | Hoechst Roussel Vet, Somerville, NJ. | 12799-809      | 10 implant cartridge, 6 pellets/implant. | Trenbolone acetate .....      | 120 mg/implant (20 mg/pellet)  |
|                    |                                      |                |  | Estradiol .....               | 24 mg/implant (4 mg/pellet)    |
| Synovex H .....    | Fort Dodge Labs, Fort Dodge, IA.     | 0856-3901      | 10 implant clip, 8 pellets/implant.      | Testosterone propionate ..... | 200 mg/implant (25 mg/pellet)  |
|                    |                                      |                |  | Estradiol benzoate .....      | 200 mg/implant (2.5 mg/pellet) |
| Synovex H .....    | Syntex Laboratories, Palo Alto, CA.  | .....          | 10 implant clip, 8 pellets/implant.      | Testosterone propionate ..... | 200 mg/implant (25 mg/pellet)  |
|                    |                                      |                |  | Estradiol benzoate .....      | 200 mg/implant (2.5 mg/pellet) |
| Synovex Plus ..... | Fort Dodge Labs, Fort Dodge, IA.     | 0856-3904      | 10 implant clip, 8 pellets/implant.      | Trenbolone acetate .....      | 200 mg/implant (25 mg/pellet)  |
|                    |                                      |                |  | Estradiol .....               | 28 mg/implant (3.5 mg/pellet)  |

In accordance with the provisions of 21 U.S.C. 811(a) of the CSA, this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1).

The Deputy Assistant Administrator, Office of Diversion Control, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. The inclusion of a product in 21 CFR 1308.26 relieves persons who handle the product in the course of legitimate business from the requirements imposed by the CSA.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the

ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Dated: September 8, 1997.

**John H. King,**  
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.  
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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

[DEA No. 160F]

**Schedules of Controlled Substances: Exempt Anabolic Steroid Products**

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Final rule.

**SUMMARY:** The interim rule (62 FR 29288, May 30, 1997) which identified ten anabolic steroid products as being exempt from certain regulatory

provisions of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*) is adopted without change.

**DATES:** *Effective Date:* October 3, 1997.

**FOR FURTHER INFORMATION CONTACT:** Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, 202-307-7183.

**SUPPLEMENTARY INFORMATION:** The Acting Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), published in the **Federal Register**, an interim rule which identified ten products as being exempt anabolic steroid products (62 FR 29288, May 30, 1997). Comments were requested, none were received.

Therefore, pursuant to the authority delegated to the Administrator of the DEA pursuant to 21 U.S.C. 871(a) and 28 CFR 0.100 and redelegated to the Deputy Assistant Administrator of the Drug Enforcement Administration Office of Diversion Control, pursuant to 28 CFR 0.104, appendix to subpart R, section 7(g)9, the Deputy Assistant Administrator of the Office of Diversion Control, hereby adopts as a final rule, without change, the interim rule amending 21 CFR 1308.34 which was published at 62 FR 29288 on May 30, 1997.

The anabolic steroid containing compounds, mixtures, or preparations which are described in 21 CFR 1308.34 are as follows:

## EXEMPT ANABOLIC STEROID PRODUCTS

| Trade name  | Company                                      | NDC No.    | Form          | Ingredients                                   | Quantity                 |
|---|--|------------|---------------|---|--------------------------|
| Andro-Estro 90-4                                      | Rugby Laboratories, Rockville Centre, NY.    | 0536-1605  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| Androgyn L.A.   | Forest Pharmaceuticals, St. Louis, MO.       | 0456-1005  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| depANDROGYN   | Forest Pharmaceuticals, St. Louis, MO.       | 0456-1020  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| DEPO-T.E.   | Quality Research Pharm., Carmel, IN.         | 52765-257  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| depTESTROGEN  | Martica Pharmaceuticals, Phoenix, AZ.        | 51698-257  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Duomone   | Wintec Pharmaceutical, Pacific, MO.          | 52047-360  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| DUO-SPAN II   | Primedics Laboratories, Gardena, CA.         | 0684-0102  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| DURATESTRIN   | W.E. Hauck, Alpharetta, GA                   | 43797-016  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Estratest   | Solvay Pharmaceuticals, Marietta, GA.        | 0032-1026  | TB            | Esterified estrogens<br>Methyltestosterone    | 1.25 mg<br>2.5 mg        |
| Estratest HS  | Solvay Pharmaceuticals, Marietta, GA.        | 0032-1023  | TB            | Esterified estrogens<br>Methyltestosterone    | 0.625 mg<br>1.25 mg      |
| Menogen   | Sage Pharmaceuticals, Shreveport, LA.        | 59243-570  | TB            | Esterified estrogens<br>Methyltestosterone    | 1.25 mg<br>2.5 mg        |
| Menogen HS  | Sage Pharmaceuticals, Shreveport, LA.        | 59243-560  | TB            | Esterified estrogens<br>Methyltestosterone    | 0.625 mg<br>1.25 mg      |
| PAN ESTRA TEST  | Pan American Labs., Covington, LA.           | 0525-0175  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Premarin with Methyltestosterone.                     | Ayerst Labs. Inc., New York, NY.             | 0046-0879  | TB            | Conjugated estrogens<br>Methyltestosterone    | 1.25 mg<br>10.0 mg       |
| Premarin with Methyltestosterone.                     | Ayerst Labs. Inc., New York, NY.             | 0046-0878  | TB            | Conjugated estrogens<br>Methyltestosterone    | 0.625 mg<br>5.0 mg       |
| Synovex H in-process bulk pellets.                    | Syntex Animal Health, Palo Alto, CA.         |            | Drum          | Testosterone propionate<br>Estradiol benzoate | 25 mg/<br>2.5 mg/pellet  |
| Synovex H in-process granulation.                     | Syntex Animal Health, Palo Alto, CA.         |            | Drum          | Testosterone propionate<br>Estradiol benzoate | 10 parts<br>1 part       |
| Synovex Plus in-process granulation.                  | Fort Dodge Animal Health, Fort Dodge, IA.    |            | Drum          | Trenbolone acetate<br>Estradiol benzoate      | 25 parts<br>3.5 parts    |
| Synovex Plus in-process bulk pellets.                 | Fort Dodge Animal Health, Fort Dodge, IA.    |            | Drum          | Trenbolone acetate<br>Estradiol benzoate      | 25 mg/<br>3.50 mg/pellet |
| Testagen  | Clint Pharmaceuticals, Nashville, TN.        | 55553-257  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| TEST-ESTRO Cypionates                                 | Rugby Laboratories, Rockville Centre, NY.    | 0536-9470  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| 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 <sup>2</sup>  |
| Testoderm with Adhesive in-process film.              | Alza Corp., Palo Alto, CA                    |            | Sheet         | Testosterone                                  | 0.25 mg/cm <sup>2</sup>  |
| Testosterone Cypionate/Estradiol Cypionate Injection. | Best Generics, No. Miami Beach, FL.          | 54274-530  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Cypionate/Estradiol Cypionate Injection. | Goldline Labs, Ft. Lauderdale, FL.           | 0182-3069  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Cyp 50 Estradiol Cyp 2.                  | I.D.E.-Interstate, Amityville, NY.           | 0814-7737  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Cypionate/Estradiol Cypionate Injection. | Schein Pharmaceuticals, Port Washington, NY. | 0364-6611  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Cypionate/Estradiol Cypionate Injection. | Steris labs, Inc., Phoenix, AZ               | 0402-0257  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Cypionate/Estradiol Cypionate Injection. | The Upjohn Co., kalamazoo, MI.               | 0009-0253  | Vial          | Testosterone cypionate<br>Estradiol cypionate | 50 mg/ml<br>2 mg/ml      |
| Testosterone Enanthate/Estradiol Valerate Injection.  | Goldline Labs, Ft. Lauderdale, FL.           | 0182-3073  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| Testosterone Enanthate/Estradiol Valerate Injection.  | Schein Pharmaceuticals, Port Washington, NY. | 0364-6618  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| Testosterone Enanthate/Estradiol Valerate Injection.  | Steris Labs. Inc., Phoenix, AZ               | 0402-0360  | Vial          | Testosterone enanthate<br>Estradiol valerate  | 90 mg/ml<br>4 mg/ml      |
| Tilapia Sex Reversal Feed (Investigational).          | Rangen, Inc., Buhl, ID                       |            | Plastic Bags. | Methyltestosterone                            | 60 mg/kg fish feed       |
| Tilapia Sex Reversal Feed (Investigational).          | Zeigler Brothers, Inc., Gardeners, PA.       |            | Plastic Bags. | Methyltestosterone                            | 60 mg/kg fish feed       |

In accordance with the provisions of 21 U.S.C. 811(a) of the CSA, this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive order (E.O.) 12866, section 3(d)(1).

The Deputy Assistant Administrator, Office of Diversion Control, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. The inclusion of a product in 21 CFR 1308.34 relieves persons who handle the product in the course of legitimate business from the registration, records, reports, prescription, physical security, import and export requirements associated with Schedule III controlled substances under the CSA. Specifically, the products are exempted from application of sections 302 through 309 and 1002 through 1004 of the CSA (21 U.S.C. 822-829 and 952-954) and §§ 1301.11, 1301.13, and 1301.71 through 1301.76 of Title 21 Code of Federal Regulations.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Dated: September 8, 1997.

**John H. King,**

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

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[CGD13-97-023]

#### Safety Zone Regulations; Interstate 5 Bridge Repair Project, Columbia River, Vancouver, WA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone for the Interstate 5 bridge repair project on the Columbia River in Vancouver, Washington. This project will run from Tuesday, September 16, 1997, from 5 a.m. (PDT) through Wednesday, October 8, 1997, at 1 p.m. (PDT). The Coast Guard, through this action, intends to protect persons, facilities, and vessels from safety hazards associated with heavy equipment and falling debris in the vicinity of the repair project. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATES:** This regulation becomes effective on September 16, 1997, at 5 a.m. (PDT) and terminates on October 8, 1997, at 1 p.m. (PDT).

**FOR FURTHER INFORMATION CONTACT:**

Lt. T.G. Allan, c/o Captain of the Port, Portland, 6767 N. Basin Ave., Portland, Oregon 97217-3992, (503) 240-9327.

**SUPPLEMENTARY INFORMATION:**

#### Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective less than 30 days from the date of publication in the **Federal Register**. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is necessary to ensure the safety of structures and vessels operating in the area of the bridge repair. Due to the complex planning and coordination involved, the event sponsor, the Oregon Department of Transportation, was unable to provide the Coast Guard with notice of the final details until 30 days prior to the date of the event. Therefore, sufficient time was not available to publish a proposed rule

in advance of the event or to provide a delayed effective date. Following normal rulemaking procedures in this case would be impracticable.

Drafting Information: The drafters of this regulation are LT T.G. Allan, Project Manager for the Captain of the Port, and LT K.A. Boodell, Project Counsel, Thirteenth Coast Guard District Legal Office.

#### Background and Purpose

The event requiring this regulation is the Oregon Department of Transportation's Interstate 5 bridge repair project. The repair project is scheduled to begin on September 16, 1997, at 5 a.m. (PDT) with work to continue twenty-four hours a day until the project is complete on or about October 8, 1997. This event may result in a large number of vessels congregating near the bridge and construction barges. To promote the safety of both spectators and workers, a safety zone is being established on the waters of the Columbia River around the repair project, and entry into this safety zone is prohibited unless authorized by the Captain of the Port. This action is necessary due to hazards associated with heavy equipment and possible debris falling into the Columbia River in the vicinity of the repair project. This safety zone will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other federal agencies.

#### Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 CFR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This expectation is based on the fact that the safety zone will restrict less than a quarter of a square mile of the waterway. The entities most likely to be affected by this action are commercial ship, and tug and barge operators on the Columbia River. These entities are aware of the Interstate bridge repair project and the safety zone, and they can schedule their transits accordingly. If safe to do so, the representative of the