bench studies and clinical trials, other relevant performance data, and labeling will ensure that minimum levels of performance, for both safety and effectiveness, are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the clitoral engorgement device before marketing the device.

On April 28, 2000, FDA issued an order to the petitioner classifying Urometrics EROS–Clitoral Therapy Device and substantially equivalent devices of this generic type into class II under the generic name, clitoral engorgement device. FDA identifies this generic type of device as a device designed to apply a vacuum to the clitoris. It is intended for use in the treatment of female sexual arousal disorder. FDA is codifying this device by adding 21 CFR 884.5970. This order also identifies the following special control applicable to this device: A special controls guidance document entitled ''Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Clitoral Engorgement Devices.''

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer of this type of device. Classification of these devices from class III to class II will relieve this manufacturer of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

List of Subjects in 21 CFR Part 884

Medical devices.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.5970 is added to subpart F to read as follows:

§ 884.5970 Clitoral engorgement device.

(a) *Identification.* A clitoral engorgement device is designed to apply a vacuum to the clitoris. It is intended for use in the treatment of female sexual arousal disorder.

(b) *Classification.* Class II (special controls). The special control is a guidance document entitled: ''Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance Document for Clitoral Engorgement Devices.''

Dated: July 17, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–19489 Filed 8–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–187F]

RIN 1117–AA51

Schedules of Controlled Substances: Exempt Anabolic Steroids Products; Republication

Editorial Note: Due to numerous printing errors, rule document FR Doc. 00-17915 originally published at 65 FR 43690-43694, Friday, July 14, 2000 is being reprinted in its entirety.

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) published an interim rule with request for comments (65 FR 3124, Jan. 20, 2000, as corrected at 65 FR 5024, Feb. 2, 2000) which identified six anabolic steroid products as being exempt from certain regulatory provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) (CSA). No comments were received. Therefore, the interim rule is being adopted without change.

EFFECTIVE DATE: July 14, 2000.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Drug

Enforcement Administration, Washington, D.C. 20537; Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION:

What Does This Rule Accomplish and by What Authority Is It Being Issued?

This rule finalizes an interim rule (65 FR 3124, Jan. 20, 2000, as corrected at 65 FR 5024, Feb. 2, 2000) which identified six products as being exempt from certain portions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) (CSA). Section 1903 of the Anabolic Steroids Control Act of 1990 (title XIX of Pub. L. 101–647) (ASCA) provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the CSA if the products have no significant potential for abuse. The procedure for implementing this section of the ASCA is described in 21 CFR 1308.33. Exempt status removes each product from application of the registration, labeling, records, reports, prescription, physical security, and import and export restrictions associated with Schedule III substances.

Why Did DEA Add Six Products to the List of Exempt Anabolic Steroids Products?

Manufacturers of six anabolic steroid products submitted exempt status applications to the Deputy Assistant Administrator for the DEA Office of Diversion Control in accordance with 21 CFR 1308.33. Each application delineated a set of facts which the applicant believed justified the exempt status of its product. The applicants provided information which they believed showed that because of the specific product preparation, concentration, mixture, or delivery system these products had no significant potential for abuse. Upon acceptance of the applications, the Deputy Assistant Administrator requested from the Assistant Secretary for Health, Department of Health and Human Services (HHS) a recommendation as to whether these products should be considered for exemption from certain portions of the CSA. The Deputy Assistant Administrator received the determination and recommendation of the Assistant Secretary for Health and Surgeon General that there was sufficient evidence to establish that each product does not possess a significant potential for abuse.

Which Anabolic Steroid Products Are Affected and When Does the Rule Become Effective?

In the interim rule, the Deputy Assistant Administrator identified the following six products as being exempt from application of sections 302 and through 309 and 1002 through 1004 of the CSA (21 U.S.C. 822–829 and 952–954) and 21 CFR 1301.13, 1301.22, and 1301.71 through 1301.76:

EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Component E–H in process granulation.	Ivy Laboratories, Inc., Overland Park, KS.	.....	Pail or drum ...	Testosterone propionate	10 parts
				Estradiol benzoate	1 part
Component E–H in process pellets.	Ivy Laboratories, Inc., Overland Parks, KS.	.....	Pail	Testosterone propionate	25 mg/
				Estradiol benzoate	2.5 mg/pellet
Component TE–S in process granulation.	Ivy Laboratories, Inc., Overland Park, KS.	.....	Pail or drum ...	Trenbolone acetate	5 parts
				Estradiol USP	1 part
Component TE–S in process pellets.	Ivy Laboratories, Inc., Overland Parks, KS.	.....	Pail	Trenbolone acetate	120 mg/
				Estradiol USP	24 mg/pellet
Testoderm with Adhesive 4 mg/d.	Alza Corp., Palo Alto,CA	Export only	Patch	Testosterone	10 mg
Testosterone Ophthalmic Solutions.	Allergan, Irvine, CA	.....	Ophthalmic Solutions.	Testosterone	≤0.6% w/v

The interim rule became immediately effective on publication in the **Federal Register,** January 20, 2000, in order to provide a health benefit to the public by more expeditiously increasing the access to these anabolic steroid products and to reduce regulatory restrictions that DEA (in consultation with HHS) has determined to be an unnecessary burden on the businesses manufacturing these products.

What Comments to the Interim Rule Were Received?

Comments to the interim rule were requested, none were received.

What Exempt Anabolic Steroid Products are Included in the List Referred to in 21 CFR 1308.34?

With the publication of this final rule, the complete list of products referred to in 21 CFR 1308.34 is 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	90 mg/ml
				Estradiol valerate	4 mg/ml
Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO.	0456–1005	Vial	Testosterone enanthate	90 mg/ml
				Estradiol valerate	4 mg/ml
Component E–H in process granulation.	Ivy Laboratories, Inc., Overland Park, KS.		Pail or drum ...	Testosterone propionate	10 parts
				Estradiol benzoate	1 part
Componenet E–H in process pellets.	Ivy Laboratories, Inc., Overland Park, KS.		Pail	Testosterone propionate	25 mg/
				Estradiol benzoate	2.5 mg/pellet
Component TE–S in process granulation.	Ivy Laboratories, Inc., Overland Park, KS.		Pail or drum ...	Trenbolone acetate	5 parts
				Estradiol USP	1 part
Component TE–S in process pellets.	Ivy Laboratories, Inc., Overland Park, KS.		Pail	Trenbolone acetate	120 mg/
				Estradiol USP	24 mg/pellet

EXEMPT ANABOLIC STEROID PRODUCTS—Continued

Trade Name	Company	NDC No.	Form	Ingredients	Quantity
depANDROGYN	Forest Pharmaceuticals, St. Louis, MO.	0456–1020	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DEPTO–T.E.	Quality Research Pharm., Carmel, IN.	52765–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Depo-Testadiol	The Upjohn Company, Kalamazoo, MI.	0009–0253	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ.	51698–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Duomone	Wintec Pharmaceutical, Pacific, MO.	52047–360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
DUO–SPAN II	Primedics Laboratories, Gardena, CA.	0684–0102	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DURATESTRIN	W. E. Hauck, Alpharetta, GA	43797–016	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Estratest	Solvay Pharmaceuticals, Marietta, GA.	0032–1026	TB	Esterifield estrogens Methyltestosterone	1.25 mg 2.5 mg
Estratest HS	Solvay Pharmaceuticals, Marietta, GA.	0032–1023	TB	Esterifield estrogens Methyltestosterone	0.625 mg 1.25 mg
Menogen	Sage Pharmaceuticals, Shreveport, LA.	59243–570	TB	Esterifield estrogens Methyltestosterone	1.25 mg 2.5 mg
Menogen HS	Sage Pharmaceutical, Shreveport, LA.	59243–560	TB	Esterifield estrogens Methyltestosterone	.0625 mg 1.25 mg
PAN ESTRA TEST	Pan American Labs., Covington, LA.	0525–0175	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Premarin with Methyltestosterone.	Ayerst Labs. Inc,. New York, NY.	0046–0878	TB	Conjugated estrogens Methyltestosterone	0.625 mg 5.0 mg
Premarin with Methyltestosterone.	Ayerst Labs. Inc., New York, NY.	0046–0879	TB	Conjugated estrogens Methyltestosterone	1.25 mg 10.0 mg
Synovex H in-process bulk pellets.	Syntex Animal health, Palo Alto, CA.		Drum	Testosterone propionate Estradiol benzoate	25 mg 2.5 mg/pellet
Synovex H in-process granulation.	Syntex Animal Health, Palo Alto, CA.		Drum	Testosterone propionate Estradiol benzoate	10 part 1 part
Synovex Plus in-process bulk pellets.	Fort Dodge Animal Health, Fort Dodge, IA.		Drum	Trenbolone acetate Estradiol benzoate	25 mg/ 3.50 mg/pellet
Synovex Plus in-process granulation.	Fort Dodge Animal Health, Fort Dodge, IA.		Drum	Trenbolone acetate Estradiol benzoate	25 parts 3.5 parts
Testagen	Clint Pharmaceuticals, Nashville, TN.	55553–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
TEST–ESTRO Cypionates	Rugby Laboratories Rockvill Centre, NY.	0536–9470	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testoderm 4 mg/d	Alza Copr., 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 4 mg/d.	Alza Corp., Palo Alto, CA	Export only	Patch	Testosterone	10 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/cm2
Testoderm with Adhesive in-process film.	Alza Corp., Palo Alto, CA		Sheet	Testosterone	0.25 mg/cm2
Testosterone Cypionate/Estradiol Cypionate Injection.	Best Generics, No. Miami Beach, FL.	54274–530	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate/Estradiol Cypionate Injection.	Goldline Labs, Ft. Lauderdale, Fl.	0182–3069	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2mg/ml
Testosterone Cyp 50 Estradiol Cyp 2.	I.D.E.-Interstate, Amityville, NY.	0814–7737	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate/Estradiol Cypionate Injection.	Schein Pharmaceuticals, Port Washington, NY.	0364–6611	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate/Estradiol Cypionate Injection.	Steris Labs. Inc., Phoenix, AZ.	0402–0257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Enanthate/Estradiol Valerate Injection.	Goldline Labs, Ft. Lauderdale, Fl.	0182–3073	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone Enanthate/Estradiol Valerate Injection.	Schein Pharmaceuticals, Port Washington, NY.	0364–6618	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone Enanthate/Estradiol Valerate Injection.	Steris Labs. Inc., Phoenix, AZ.	0402–0360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone Ophthalmic Solutions.	Allergan, Irvine, CA		Ophthalmic solutions.	Testosterone	≤0.6% w/v
Tilapia Sex Reversal Feed (Investigational).	Rangen, Inc., Buhl, ID		Plastic bags	Methyltestosterone	60 mg/kg fish feed

EXEMPT ANABOLIC STEROID PRODUCTS—Continued

Trade Name	Company	NDC No.	Form	Ingredients	Quantity
Tilapia Sex Reversal Feed (Investigational).	Ziegler Brothers, Inc., Gardners, PA.		Plastic bags ...	Methyltestosterone	60 mg/kg fish feed

Additional copies of this list may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, for the DEA 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 significant economic impact on a substantial number of small business entities. The granting of exempt status relieves persons who handle the exempt products in the course of legitimate business from the registration, labeling, records, reports, prescription, physical security, and import and export restrictions imposed by the CSA.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, section 1(b). The Office of Management and Budget (OMB) reviewed the interim rule as a significant action; the DEA received no comments regarding the interim rule. This final rule falls into a category of regulatory actions which OMB has determined are exempt from regulatory review. Therefore, this action has not been reviewed by the OMB.

Executive Order 13132

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132 and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act of 1995

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.

Small Business Regulatory Enforcement Fairness Act of 1996

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 significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

PART 1308—[AMENDED]

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), the Deputy Assistant Administrator of the Office of Diversion Control hereby adopts as a final rule, without change, the interim rule which was published at 65 FR 3124 on Jan. 20, 2000 and corrected at 65 FR 5024, on Feb. 2, 2000, amending the list described in 21 CFR 1308.34.

Dated: July 3, 2000.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 00–17915 Filed 7–13–00; 8:45 am]

Editorial Note: Due to numerous printing errors, rule document FR Doc. 00-17915 originally published at 65 FR 43690-43694, Friday, July 14, 2000 is being reprinted in its entirety.

[FR Doc. R0–17915 Filed 8–1–00; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA–156F]

RIN # 1117–AA43

Listed Chemicals; Final Establishment of Thresholds for Iodine and Hydrochloric Gas (Anhydrous Hydrogen Chloride)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule with request for comment.

SUMMARY: Effective October 3, 1996, the Comprehensive Methamphetamine Control Act of 1996 (MCA) established that iodine is a List II chemical; however, it was not made subject to import/export regulatory controls. While exports of the listed chemical hydrochloric acid (including anhydrous hydrogen chloride, referred to in the MCA as hydrochloric gas, which is a form of hydrogen chloride) were already regulated pursuant to 21 CFR 1310, the MCA had the practical effect of directing the DEA to place domestic controls on anhydrous hydrogen chloride. Since no domestic thresholds for iodine or anhydrous hydrogen chloride have been established prior to this Final Rule, all domestic transactions involving such chemicals have been subject to recordkeeping and reporting requirements under the Controlled Substances Act since October 3, 1996.

This rule establishes a domestic threshold of zero (0.0 kilograms) for anhydrous hydrogen chloride, and a domestic threshold of 0.4 kilograms for iodine. Import and export transactions in anhydrous chloride are unaffected by this rule. Iodine transactions involving amounts below the threshold will not be subject to recordkeeping and reporting requirements except for reporting of any unusual or excessive loss or disappearance as required by 21 U.S.C. 830(b)(1)(C).

Although the threshold for anhydrous hydrogen chloride is established at 0.0 kilogram, DEA has concluded that certain transactions in anhydrous hydrogen chloride are not sources for