or one other party), until such time as the Gas Service Provider commences service to serve a second shipper, or the Commission determines that the Gas Service Provider's denial of a request for service is unjustified;

(2) A Gas Service Provider that serves exclusively shippers with ownership interests in both the pipeline operated by the Gas Service Provider and the gas produced from a field or fields connected to that single pipeline or pipelines, until such time as the Gas Service Provider commences service to a non-owner shipper, or the Commission determines that the Gas Service Provider's denial of a request for service is unjustified;

(3) Any pipeline or class of pipelines which feeds into a facility where gas is first collected or a facility where gas is first separated, dehydrated, or otherwise processed; and

* * * * *

(b) A Gas Service Provider that makes no filing pursuant to §§ 330.3(a)(1) or (a)(2) becomes subject to the § 330.2 reporting requirements at any time that it no longer meets the §§ 330.3(a)(1) or (a)(2) criteria. A Gas Service Provider that becomes subject to reporting during any calender quarter must submit a § 330.2 report on the 15th day of the following quarter. Gas Service Providers must comply with the § 330.2 reporting requirements as directed by the Commission.

(c) When a Gas Service Provider subject to the § 330.2 reporting requirements alters its affiliates, customers, rates, conditions of service, or facilities during any calender quarter, it must then file with the Commission, on the 15th day of the following quarter, a revised report describing all alterations occurring during the previous quarter.

[FR Doc. 00–19426 Filed 8–1–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 00P–1282]

Obstetrical and Gynecological Devices; Classification of the Clitoral Engorgement Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the clitoral engorgement device into class II (special controls). The special control that will apply is a guidance document entitled: ''Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance Document for Clitoral Engorgement Devices.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the FDA Modernization Act of 1997. The agency is classifying the clitoral engorgement device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective September 1, 2000.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on April 25, 2000, classifying the Urometrics EROS–Clitoral Therapy Device into class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or to a device that was subsequently reclassified into class I or class II. On April 27, 2000, FDA filed a petition submitted by Urometrics, requesting classification of the Urometrics EROS–Clitoral Therapy Device into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Urometrics EROS–Clitoral Therapy Device can be classified in class II with the establishment of special controls. This device is indicated for use in women with female sexual arousal disorder, which can present with symptoms of diminished vaginal lubrication, diminished clitoral and genital engorgement, lowered sexual satisfaction, and a reduced ability to achieve orgasm. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated specifically with this type of device: Unknown effects of extended use, and improper use of the device due to misplacement, or use of the device over compromised tissue. In addition to the general controls of the act, this type device is subject to the following special control: A special controls guidance document entitled ''Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Clitoral Engorgement Devices.''

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the device is not exempt from premarket notification requirements. FDA review of key design features, data sets from

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