is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background

On January 18, 2011, President Obama signed E.O. 13563, Improving Regulations and Regulatory Review, directing agencies to develop a plan for a retrospective analysis of existing regulations. NASA developed its plan and published it on the Agency's open Government Web site at *http://www.nasa.gov/open/*. The Agency conducted an analysis of its existing regulations to comply with the Order and determined that subpart 1216.2, Floodplain and Wetlands Management, should be repealed.

Subpart 1216.2 was promulgated January 4, 1979, [44 FR 1089] in response to Executive Order (E.O.) 11988, Floodplain Management, and E.O. 11990, Protection of Wetlands. Neither E.O. mandates that these requirements be codified in the CFR. For example, E.O. 11988 subsection 2(d) states in pertinent part ''. . . each agency shall issue or amend existing regulations and procedures . . .;'' and E.O. 11990 section 6 states in pertinent part ''. . . agencies shall issue or amend their existing procedures . . .'' Therefore, this subpart will be repealed because it is now captured in NASA Interim Directive (NID) 8500.100, Floodplain and Wetlands Management. NID 8500.100 is accessible at *http://nodis3.gsfc.nasa.gov/OPD_docs/NID_8500_100_.pdf*.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113 (a), authorizes the Administrator of NASA to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improvement Regulation and Regulation Review

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated as ''not significant'' under section 3(f) of E.O. 12866.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 U.S.C. 603). This rule removes two subparts from Title 14 of the CFR that are already reflected in existing NASA internal requirements and, therefore, does not have a significant economic impact on a substantial number of small entities.

Review Under the Paperwork Reduction Act

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Review Under E.O. 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any substantial direct effects on state and local governments within the meaning of the E.O. Therefore, no Federalism assessment is required.

List of Subjects in 14 CFR Part 1216

Flood plains.

PART 1216—ENVIRONMENTAL POLICY

■ Accordingly, under the authority of the National Aeronautics and Space Act, as amended (51 U.S.C. 20113), NASA amends 14 CFR part 1216 by removing and reserving subpart 1216.2, consisting of §§ 1216.200 through 1216.205.

Cheryl E. Parker,

NASA Federal Register Liaison Officer.

[FR Doc. 2015–12914 Filed 5–27–15; 8:45 am]

BILLING CODE 7510–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2015–N–1297]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the vibrator for climax control of premature ejaculation into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the classification of the vibrator for climax control of premature ejaculation. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective May 28, 2015. The classification was applicable on March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Tuan Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G118, Silver Spring, MD 20993–0002, 301–796–5174, *tuan.nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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), 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 FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On November 21, 2013, Ergon Medical, Ltd., submitted a request for classification of the Prolong™ under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 20, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5025.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a vibrator for climax control of premature ejaculation will need to comply with the special controls named in this final order. The device is assigned the generic name vibrator for climax control of premature ejaculation, and it is identified as a device used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1.

TABLE 1—VIBRATOR FOR CLIMAX CONTROL OF PREMATURE EJACULATION RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Pain or Discomfort due to Misuse of Device.	Labeling.
Burns	Electrical and Thermal Safety Testing.
	Labeling.
Electrical Shock	Electrical Safety Testing.
	Labeling.
Adverse Skin Reactions.	Biocompatibility Testing.
Patient Injury due to Device Breakage or Failure.	Mechanical Safety Testing.
	Labeling.
Interference With Other Devices/Electrical Equipment.	Electromagnetic Compatibility Testing.
	Labeling.

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- The labeling must include specific instructions regarding the proper placement and use of the device.
- The portions of the device that contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.
- Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the vibrator for climax control of premature ejaculation they intend to market.

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. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*.

1. DEN130047: De Novo Request per 513(f)(2) from Ergon Medical Ltd., dated November 21, 2013.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

■ 1. The authority citation for 21 CFR part 876 continues to read as follows:

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

■ 2. Add § 876.5025 to subpart F to read as follows:

§ 876.5025 Vibrator for climax control of premature ejaculation.

(a) *Identification.* A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The labeling must include specific instructions regarding the proper placement and use of the device.

(2) The portions of the device that contact the patient must be demonstrated to be biocompatible.

(3) Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.

(4) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12852 Filed 5–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 243

[Docket ID: DOD–2013–OS–0130]

RIN 0790–AJ08

Ratemaking Procedures for Civil Reserve Air Fleet Contracts

AGENCY: USTRANSCOM, DoD.

ACTION: Final rule.

SUMMARY: Section 366 of the National Defense Authorization Act for Fiscal Year 2012 directs the Secretary of Defense to determine a fair and reasonable rate of payment for airlift services provided to the Department of Defense by air carriers who are participants in the Civil Reserve Air Fleet Program. The Department of Defense (the Department or DoD) is promulgating regulations to establish ratemaking procedures for civil reserve air fleet contracts as required by Section 366(a) in order to determine a fair and reasonable rate of payment.

DATES: This final rule is effective on June 29, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Gates, Chief, Acquisition Law, USTRANSCOM/TCJA, (618) 220–3982 or Mr. Jeff Beyer, Chief, Business Support and Policy Division, USTRANSCOM/TCAQ, (618) 220–7021.

SUPPLEMENTARY INFORMATION:

Background

The Civil Reserve Air Fleet (CRAF) is a wartime readiness program, based on the Defense Production Act of 1950, as amended, (50 U.S.C. App. 2601 *et seq.*), and Executive Order 13603 (National Defense Resource Preparedness), March 16, 2012, to ensure quantifiable, accessible, and reliable commercial airlift capability to augment DoD airlift and to assure a mobilization base of aircraft available to the Department of Defense for use in the event of any level of national emergency or defense-orientated situations. As a readiness program, CRAF quantifies the number of passenger and cargo commercial assets required to support various levels of wartime requirements and thus allows DoD to account for their use when developing and executing contingency operations and war plans. In addition, the CRAF program identifies how DoD gains access to these commercial assets for operations by defining the authorities and procedures for CRAF activation. Finally, the program helps ensure that the DoD has reliable lines of communication and a common understanding of procedures with the carriers.

The United States Transportation Command (USTRANSCOM) negotiates and structures award of aircraft service contracts with certificated civilian air carriers willing to participate in the CRAF program in order to ensure that a mobilization base of aircraft is capable of responding to any level of defense-orientated situations.

The ability to set rates maintains the CRAF program's great flexibility to have any air carrier in the program able to provide aircraft within 24 hours of activation to fly personnel and cargo to any location in the world at a set rate per passenger or ton mile, regardless of where the air carrier normally operates. It also provides the Secretary of Defense the ability to respond rapidly to assist in emergencies and approved humanitarian operations, both in the United States and overseas where delay could result in more than monetary losses. The Government-set rate allows contracts to any location, sometimes awarded within less than an hour, and provides substantial commercial capability on short notice.

During the initial CRAF program years (between 1955 and 1962), ratemaking to price DoD airlift service relied upon price competition to meet its commercial airlift needs. This procurement method resulted in predatory pricing issues and failed to provide service meeting safety and performance requirements. Congressional Subcommittee hearings held at the time determined price competition to be non-compensatory and destructive to the industry. As a result, the ratemaking process was implemented under the regulatory authority of the Civil Aeronautics Board (CAB). Ratemaking continued under the CAB until deregulation in 1980. At that time, civil air carriers and DoD's contracting agency for long-term international airlift, the Military Airlift Command (MAC), agreed by a memorandum of understanding (MOU) that CAB methodologies by which rates for DoD airlift were established produced fair and reasonable rates and furthered the objectives of the CRAF program; and therefore, the parties agreed to continue to use CAB methodologies for establishing MAC uniform negotiated rates under an MOU renewed every five years. MAC became Air Mobility Command (AMC) on June 1, 1992. Ratemaking continued under AMC until January 1, 2007, when DoD's contracting authority for long-term international airlift was transferred from AMC to USTRANSCOM. On December 31, 2011, the National Defense