

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	FDA Form Nos.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supporting data for reclassification petition .....	.....	6	1	6	497	2,982
Supplemental Data Sheet .....	3427	6	1	6	1.5	9
General Device Classification Questionnaire ..	3429	6	1	6	1.5	9
Total .....	.....	.....	.....	.....	.....	3,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on reclassification petitions received in the last 3 years, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

This document refers to previously approved collections of information found in 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 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231.

Dated: June 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–14358 Filed 6–11–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–P–1197]

#### Medical Devices; Exemption From Premarket Notification: Electric Positioning Chair

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for an electric

positioning chair with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit either electronic or written comments by July 13, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2015–P–1197, by any of the following methods:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### *Written Submissions*

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jismi Johnson, Center for Devices and Radiological Health (CDRH), Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993–0002, 301–796–6424, [jismi.johnson@fda.hhs.gov](mailto:jismi.johnson@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Statutory Background**

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls) 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 such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section

510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added a new section, 510(m), to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

## II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance is available through the Internet at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/>

*GuidanceDocuments/UCM080199.pdf*. Send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

## III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Brian Orwat, Stryker Medical, 3800 East Centre Ave., Portage, MI 49002 for its electric positioning chair classified under 21 CFR 890.3110.

## IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-14434 Filed 6-11-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-2001]

### Assessment of Male-Mediated Developmental Risk for Pharmaceuticals; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Assessment of Male-Mediated Developmental Risk for Pharmaceuticals." This draft guidance provides recommendations to sponsors for assessing risks to embryo/fetal development resulting from administration of an active pharmaceutical ingredient (API) to males either through an effect on the

male germ cell or from fetal exposure following seminal transfer of a potentially developmental toxicant to pregnant females. The need for measures to mitigate the risk to embryo/fetal development posed by males participating in clinical trials is also addressed.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 11, 2015.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lynnda Reid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5388, Silver Spring, MD 20993-0002, 301-796-0984.

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Assessment of Male-Mediated Developmental Risk for Pharmaceuticals." This guidance presents an overview of FDA's current approach to assessing potential risks associated with pharmaceutical use in male patients. Current regulatory guidance exists regarding the need to assess the genotoxic and embryo/fetal developmental toxicity potential of pharmaceuticals before their administration to pregnant women and females of reproductive potential. However, there is a lack of consistency in clinical trial protocol designs and labeling documents regarding pregnancy risk for sexual partners of men being administered an API. The concept of a female sexual partner may be subject to developmental risk associated with