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* 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]

BILLING CODE 4164–01–P

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 conceptus of a female sexual partner may be subject to developmental risk associated with

pre- or post-conception exposure of a male to an API. Such male-mediated developmental toxicity may result from an effect of the API on the male germ cell before conception or occur as a result of direct exposure of the conceptus to the pharmaceutical following seminal transfer and vaginal uptake in a pregnant partner.

This draft guidance provides recommendations for addressing the potential for male-mediated adverse effects on pregnancy outcome for sponsors developing an investigational drug. Topics covered include: (1) Factors that investigators should consider when testing a new API in males, (2) nonclinical studies relevant to the assessment of male-mediated developmental risks, and (3) measures to prevent pregnancy or seminal transfer to a pregnant sexual partner when risk is either unknown or anticipated.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the assessment of male-mediated developmental risk for pharmaceuticals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 312 have been approved under OMB control number 0910–0014.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14363 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–2013–E–1656]

Determination of Regulatory Review Period for Purposes of Patent Extension; XELJANZ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XELJANZ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product XELJANZ (tofacitinib citrate). XELJANZ is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Subsequent to this approval, the USPTO received a patent term restoration application for XELJANZ (U.S. Patent No. RE41,783) from Pfizer Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 26, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XELJANZ represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XELJANZ is 3,947 days. Of this time, 3,564 days occurred during the testing phase of the regulatory review period, while 383 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 18, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 18, 2002.