documents will be available Wednesday, June 11, 2014, at the following Web site: *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.*

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13758 Filed 6–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 30 and 31, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993–0002, *Sara.Anderson@fda.hhs.gov*, 301–796–7047, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 30, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Ablatherm Integrated Imaging device sponsored by EDAP Technomed, Inc. The proposed Indication for Use for the Ablatherm Integrated Imaging device, as stated in the PMA, is as follows:

The Ablatherm Integrated Imaging device is intended for the primary treatment of prostate cancer in subjects with low risk, localized prostate cancer.

On July 31, 2014, the committee will discuss and make recommendations regarding the classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatoceles. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Penile Tumescence Monitors are currently regulated under the heading, ''Monitor, Penile Tumescence,'' Product Code LIL, as unclassified under the 510(k) premarket notification authority. Nephrostomy Catheters are currently regulated under the heading, ''Catheter, Nephrostomy,'' Product Code LJE, as unclassified under the 510(k) premarket notification authority. Stimulators for Electrical Sperm Collection are currently regulated under the heading, ''Stimulator, Electrical for Sperm Collection,'' Product Code LNL, as unclassified under the 510(k) premarket notification authority. Erectile Dysfunction Devices are currently regulated under the heading, ''Device, Erectile Dysfunction,'' Product Code LST, as unclassified under the 510(k) premarket notification authority. Alloplastic Spermatoceles are currently regulated under the heading, ''Spermatocele, Alloplastic,'' Product Code LQS, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness and the regulatory classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatoceles.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 24, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 30, 2014, and between approximately 8:50 a.m. and 9:50 a.m. on July 31, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 16, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 17, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at *James.Clark@fda.hhs.gov*, or 301–796–5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 6, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–13650 Filed 6–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0157]

Determination of Regulatory Review Period for Purposes of Patent Extension; Arcapta Neohaler

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Arcapta Neohaler 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 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 Arcapta Neohaler (indacaterol maleate). Arcapta Neohaler is indicated for long term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Arcapta Neohaler (U.S. Patent No. 6,878,721) from Novartis AG, and USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised USPTO that this human drug product had undergone a regulatory review period and that the approval of Arcapta Neohaler represented the first permitted commercial marketing or use of the product. Thereafter, USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Arcapta Neohaler is 3,097 days. Of this time, 2,171 days occurred during the testing phase of the regulatory review period, while 926 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 9, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 9, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 18, 2008. The applicant claims December 19, 2008, as the date the new drug application (NDA) for Arcapta Neohaler (NDA 22–383) was initially submitted. However, FDA records indicate that NDA 22–383 was submitted on December 18, 2008.

3. *The date the application was approved:* July 1, 2011. FDA has verified the applicant's claim that NDA 22–383 was approved on July 1, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,597 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 11, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 9, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13638 Filed 6–11–14; 8:45 am]

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