Section 8.2.3 of the Guide, ''Support on Data Validation Rules,'' states that ''[t]he Standards Web page provides links to the validation rules needed to ensure data compliance with CDISC standards, such as SDTM, SEND, ADaM, and define.xml.'' In this notice, we are announcing the availability of the SEND validation rules.

The Validation Rules for SEND Formatted Studies is an Excel file that provides human readable description of a rule set for validation (*Nonclinical Validator Specifications (XLS)*). Submitters of nonclinical study data can use this information to identify how FDA validates the data. It is available from the FDA Study Data Standards Resources Web page: *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm.* The file contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support meaningful analysis). The file may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

The validation rules in the Nonclinical Validator Specifications document were created following the suggested human readable validation rule syntax published by a Computational Science Symposium workgroup. This document is available at: *http://www.phusewiki.org/wiki/index.php?title=Guidelines_for_Validation_Rule_Developers.*

Dated: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11522 Filed 5–19–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Circulatory System 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: Circulatory System 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 June 12, 2014, from 8 a.m. to 6 p.m. *Location:* Holiday Inn Express/Highlands, 20260 Goldenrod Lane, Germantown, MD 20876. The hotel telephone number is 301–428–1300.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 *Jamie.Waterhouse@fda.hhs.gov,* 301–796–3063, 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 June 12, 2014, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the LUTONIX 035 Drug Coated Balloon PTA Catheter sponsored by Lutonix, Inc. The LUTONIX 035 Drug Coated Balloon PTA Catheter (LUTONIX DCB) is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter with a paclitaxel-based drug coating on the surface of the balloon. The LUTONIX DCB is compatible with a 0.035'' guidewire and has balloon sizes ranging from 4 millimeters (mm) to 6 mm in diameter and 40 mm to 100 mm in length. The LUTONIX DCB catheter is available in 75 centimeters (cm), 100 cm and 130 cm working lengths.

The proposed indications for use are for improving luminal diameter for the treatment of obstructive de novo or non-stented restenotic lesions (≤15cm in length) in native femoropopliteal arteries having reference vessel diameters of 4 mm to 6 mm.

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 4, 2014. On June 12, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 May 28, 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 May 30, 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 AnnMarie Williams, Conference Management Staff, at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 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: May 14, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–11553 Filed 5–19–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–1226]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PICATO 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 Patents and Trademarks, 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 Patents and Trademarks 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 PICATO (ingenol mebutate). PICATO is indicated for the topical treatment of actinic keratosis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PICATO (U.S. Patent No. 7,410,656) from Leo Laboratories Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 22, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PICATO represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PICATO is 2,737 days. Of this time, 2,432 days occurred during the testing phase of the regulatory review period, while 305 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:* July 28, 2004. The applicant claims July 9, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 28, 2004, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 25, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for Picato (NDA 202833) was submitted on March 25, 2011.

3. *The date the application was approved:* January 23, 2012. FDA has verified the applicant's claim that NDA 202833 was approved on January 23, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 783 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 July 21, 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 November 17, 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: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11521 Filed 5–19–14; 8:45 am]

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