and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–31774 Filed 12–17–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Peripheral and Central Nervous System Drugs 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: Peripheral and Central Nervous System Drugs 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 January 22, 2016, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *PCNS@fda.hhs.gov,* 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: The committee will discuss new drug application 206488, eteplirsen injection for intravenous infusion, sponsored by Sarepta Therapeutics, Inc., for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

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 January 7, 2016. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 2:40 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 December 29, 2015. 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 December 30, 2015.

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 disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi 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: December 11, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–31825 Filed 12–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0474]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XTANDI 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.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 16, 2016. 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

June 15, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–E–0474 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; XTANDI.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 XTANDI (enzalutamide). XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. Subsequent to this approval, the USPTO received a patent term restoration application for XTANDI (U.S. Patent No. 8,183,274) from The Regents of the University of California, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2013, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XTANDI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for XTANDI is 1,892 days. Of this time, 1,790 days occurred during the testing phase of the regulatory review period, while 102 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:* June 29, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 29, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 22, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for XTANDI (NDA 203–415) was initially submitted on May 22, 2012.

3. *The date the application was approved:* August 31, 2012. FDA has verified the applicant's claim that NDA 203–415 was approved on August 31, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 101 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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: December 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31824 Filed 12–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Intent To Establish the 2018 Physical Activity Guidelines Advisory Committee and Solicitation of Nominations for Appointment to the Committee Membership

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the intent to establish a Physical Activity Guidelines Advisory Committee (Committee). It is planned for the Committee to be established in calendar year 2016. This notice also serves to announce that an invitation is being extended for nominations of qualified candidates to be considered for appointment as a member of the Committee.

DATES: Nominations for membership on the Committee must be submitted by 6:00 p.m. ET on Friday, February 5, 2016.

ADDRESSES: Nominations should be submitted by email to *PAGACnominations@hhs.gov.* This address can be accessed online at the following address: *www.health.gov/paguidelines.* Nominations may also be sent to the following address: Richard D. Olson, M.D., M.P.H., Designated Program Official, 2018 Physical Activity Guidelines Advisory Committee; HHS/OASH/ODPHP; 1101 Wootton Parkway, Suite LL–100; Rockville, MD 20852; Telephone: (240) 453–8280.

FOR FURTHER INFORMATION CONTACT: Designated Program Official, 2018 Physical Activity Guidelines Advisory Committee, Richard D. Olson and/or Alternate Designated Program Official, Katrina L. Piercy, Ph.D., R.D., HHS/OASH/ODPHP; 1101 Wootton Parkway, Suite LL–100; Rockville, MD 20852; Telephone: (240) 453–8280. Additional information is available at *www.health.gov/paguidelines.*

SUPPLEMENTARY INFORMATION:

Purpose: The inaugural *Physical Activity Guidelines for Americans* (PAG), issued in 2008, represents the first major federal review of the benefits of physical activity. The PAG provides science-based advice on how physical activity can help promote health and reduce the risk of chronic disease. The PAG serves as the benchmark and primary, authoritative voice of the federal government for providing science-based guidance on physical activity, fitness, and health in the United States. Five years after the first edition of the PAG was released, ODPHP, in collaboration with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the President's Council on Fitness, Sports, and Nutrition (PCFSN) led development of the *PAG Midcourse Report: Strategies to Increase Physical Activity Among Youth.* The 2nd edition of the *Physical Activity Guidelines* will build upon the 1st edition and provide a foundation for federal recommendations and education for physical activity programs for Americans, including those at risk for chronic disease.

The Committee will be established as a discretionary federal advisory committee and governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.). The work of the Committee will be solely advisory in nature and time-limited. Formation of the Committee is necessary and in the public interest. The Committee will examine the current PAG, take into consideration new scientific evidence and current resource documents, and then develop a scientific advisory report to be submitted to the Secretary of HHS that outlines its science-based recommendations and rationale. The scientific report will be used by the federal government to develop the 2nd edition of the *Physical Activity Guidelines for Americans.* The Committee's duties do not include developing the policy, a draft of the policy, or determining how future policy might be implemented by the federal government. For those interested in reviewing the *Physical Activity Guidelines for Americans,* the 2008 Advisory Committee Scientific Report, or the PAG Midcourse Report, they are available at *www.health.gov/paguidelines.*

The Committee is expected to begin meeting in summer of 2016. The Committee is expected to meet approximately five times during the course of its operation. Pursuant to FACA, all meetings of the full Committee will be open to the public.

Individuals selected for appointment to the Committee will be invited to serve as members until the charter expires or the Committee accomplishes its mission. In keeping with FACA, the charter will expire two years from the date it is established. The Committee will operate until its report is delivered to the Secretary or the charter expires, whichever comes first. There will be no