approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We require that Medicare Advantage organizations and Prescription Drug Plans complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (*www.medicare.gov*, the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and enrollment. The package has been revised subsequent to the publication of the 60-day **Federal Register** notice (September 24, 2015; 80 FR 57619). *Form Number:* CMS–10142 (OMB control number 0938–0944); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410–786–3026).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Contract Year 2017 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* We require that Medicare Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on *www.medicare.gov* and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. The package has been revised subsequent to the publication of the 60-day Federal Register notice (September 24, 2015; 80 FR 57619). *Form Number:* CMS–R–262 (OMB control number 0938–0763); *Frequency:* Yearly; *Affected Public:* Private sector (business or other for-profits and not-for-profit institutions); *Number of Respondents:* 552; *Total Annual Responses:* 5,448; *Total Annual Hours:* 52,902. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209).

Dated: December 15, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–31887 Filed 12–17–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Disaster Information Collection Form.

OMB No.: 0970—NEW.

Description: This is a request by the Administration for Children and Families (ACF) for a generic clearance for the Disaster Information Collection Form. An approval for a generic clearance is being requested because each of the thirteen program offices within ACF has a slightly different need for information about program impact information collection during a disaster.

ACF oversees more than 60 programs that affect the normal day to day operations of families, children, individuals and communities in the United States. Many of these programs encourage grantees or state administrators to develop emergency preparedness plans, but do not have statutory authority to require these plans be in place. ACF facilitates the inclusion of emergency preparedness planning and training efforts for ACF programs.

Presidential Policy Directive–8 (PPD–8) provides federal guidance and planning procedures under established phases—protection, preparedness, response, recovery, and mitigation. The Disaster Information Collection Forms addressed in this clearance process provide assessment of ACF programs in disaster response, and recovery.

ACF/Office of Human Services Emergency Preparedness and Response (OHSEPR) has a requirement under PPD–8, the National Response Framework, and the National Disaster Recovery Framework to report disaster impacts to ACF-supported human services programs to the HHS Secretary's Operation Center (SOC) and interagency partners. ACF/OHSEPR works in partnership with the Assistant Secretary for Preparedness and Response (ASPR), and the Federal Emergency Management Agency (FEMA) to report assessments of disaster impacted ACF programs and the status of continuity of services and recovery.

Respondents: State administrators, and/or ACF grantees.

Annual Burden Estimates: The burden cap for the Disaster Information Collection Form is estimated based on a single disaster per year. The estimate is for approximately 10 state administrators, or grantees to go through all of the applicable questions with the Regional and Central Office staff. Some ACF programs have more questions and may have more respondents.

Instrument	Number of respondents	Number of responses per respondent	Burden hours per response	Total burden hours
Disaster Information Collection Form	10	15	0.08 hours (5 minutes)	1.25 hours (75 minutes).

An estimate of the number of disasters that would warrant data collection is difficult to calculate due to the unpredictable nature of disasters. For example, in 2012, there were 95 disasters nationwide but OHSEPR did not collect data on all of them because they had minimal effects on ACF programs.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30

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