submit a non-binding letter of intent by March 15, 2013, and an application by May 1, 2013.

On July 17, 2013, we published a notice in the **Federal Register** announcing an extension of deadlines. The new deadlines were July 19, 2013 for the Letter of Intent and August 1, 2013 for the application.

II. Provisions of the Notice

Since the publication of the July 17, 2013 notice, several stakeholders have requested additional time to prepare their applications and form partnerships. Therefore, for the Comprehensive ESRD Care Initiative, the Innovation Center is reopening the Letters of Intent submission period and extending the deadlines for submission of both the Letters of Intent and the Applications to August 30, 2013.

In the **DATES** section of this notice, we are including the new submissions deadlines. For additional information on the Comprehensive ESRD Care Model and how to apply, we refer readers to click on the Request for Applications located on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/comprehensive-ESRD-care.*

(No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: August 5, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–19351 Filed 8–8–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Home Visiting: Approaches to Father Engagement and Father's Experiences.

OMB No.: New Collection.

Description: The Office of Planning, Research, and Evaluation (OPRE) in the Administration for Children and Families (ACF) is proposing an information collection activity for the Home Visiting: Approaches to Father Engagement and Father's Experiences Study.

This study will document strategies used by home visiting programs to engage and serve fathers and the perceptions of the fathers regarding the programs. The findings will be of broad interest to many home visiting programs that desire to increase the active engagement of fathers.

Data collection will involve semi-structured discussions and interviews with administrators and managers of select home visiting programs as well as staff about the objectives, experiences, and specific methods and approaches used by program operators that have successfully engaged fathers.

Data collection will also include semi-structured discussions and interviews with invited and/or participating fathers about their expectations, perceptions, and opinions of the home visiting program and experiences with the program.

Respondents: Administrators and managers of select home visiting programs, home visiting staff, and participating and invited fathers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Discussion Guide for use with Fathers	250	83	1	2	166
Discussion Guide for use with Home Visiting Program Administrators, Managers, and Staff	50	17	1	2	34

Estimated Total Annual Burden Hours: 200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer, Administration for Children and Families.

[FR Doc. 2013–19337 Filed 8–8–13; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug User Fee Cover Sheet; Form FDA 3397'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, 1350 Piccard

Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 6, 2012, the Agency submitted a proposed collection of information entitled ''Prescription Drug User Fee Cover Sheet; Form FDA 3397'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0297. The approval expires on December 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: August 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19276 Filed 8–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Oncologic 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: Oncologic 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 September 12, 2013, from 8 a.m. to 5 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. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, 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, email: *ODAC@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: On September 12, 2013, the committee will discuss supplemental biologics license application 125409/51, with the trade name PERJETA (pertuzumab) injection, application submitted by Genentech, Inc. The proposed indication (use) for this product is in combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (tumor greater than 2 cm in diameter) as part of a complete early breast cancer regimen containing either fluorouracil, epirubicin, and cyclophosphamide or carboplatin.

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 August 28, 2013. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 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 August 20, 2013. 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 August 21, 2013.

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 Caleb Briggs 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: August 2, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–19252 Filed 8–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Anti-Infective 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