ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
12 Month Follow-up Survey	3,600	1	0.833	2,999
Tracking Letters	10,800	3	0.083	2,689
Baseline Information Form (Modification)	3,500	1	0.05	175
Program Leadership/Managers Interview Guide	13	1	2	26
Instructional Staff Interview Guide	21	1	2	42
Case Managers/Advisors Interview Guide	16	1	2	32
Partners Interview Guide	16	1	2	32
Employers Interview Guide	19	1	1	19
Instructional Staff Survey	26	1	0.5	13
Case Managers/Advisors Survey	24	1	0.5	12
Study Participant Interview Guide	80	1	1	80

Estimated Total Annual Burden Hours: 6,119.

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. 2012–17641 Filed 7–19–12; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0247]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 20, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription Drug User Fee Act (PDUFA) Products—(OMB Control Number 0910–0429)—(Extension)

This information collection approval request is for FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the Agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (FDAMA), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an End-of-Phase 2 meeting and a Pre-NDA meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

A. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the Agency as part of an Investigational New Drug Application (IND), New Drug Application (NDA), or Biological License Application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: Form FDA 1571—OMB control number 0910 0014, and Form FDA 356h—OMB control number 0910 0338.

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the Agency with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the Agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the Agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes:

- Information identifying and describing the product;
- The type of meeting being requested;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes from the meeting;
- A preliminary proposed agenda;
- A draft list of questions to be raised at the meeting;
- A list of individuals who will represent the sponsor or applicant at the meeting;
- A list of Agency staff requested to be in attendance;
- The approximate date that the information package will be sent to the Agency; and
- Suggested dates and times for the meeting.

This information will be used by the Agency to determine the utility of the meeting, to identify Agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

A sponsor or applicant submitting an information package to the Agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or Agency. The Agency recommends that information packages generally include:

- Identifying information about the underlying product;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes of the meeting;
- A proposed agenda for the meeting;
- A list of specific questions to be addressed at the meeting;
- A summary of clinical data that will be discussed (as appropriate);
- A summary of preclinical data that will be discussed (as appropriate); and
- Chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant. The Agency finds that reviewing such information is critical to achieving a productive meeting.

The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to INDs, NDAs, and BLAs and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an End-of-Phase 2 meeting (§ 312.47(b)(1)(ii) and (b)(1)(iv)) and a Pre-NDA meeting (§ 312.47(b)(2)).

Description of Respondents: A sponsor or applicant for a drug or biological product who requests a formal meeting with the Agency regarding the development and review of a PDUFA product.

Burden Estimate: Provided below is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

C. Request for a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 975 sponsors and applicants (respondents) request approximately 2,014 formal meetings with CDER annually and approximately 127 respondents request approximately 253 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 10 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

D. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 756 respondents submitted approximately 1,394 information packages to CDER annually and approximately 112 respondents submitted approximately 203 information packages to CBER annually prior to a formal meeting regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with the guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency.

As stated earlier, the guidance provides information on how the Agency will interpret and apply section 119(a) of FDAMA, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47

and 312.82). The information collection provisions in § 312.47 concerning End-of-Phase 2 meetings and Pre-NDA meetings have been approved by OMB (OMB control number 0910 0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request.

In the **Federal Register** of March 20, 2012 (77 FR 16235), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments on the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Meeting requests and information packages	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests:					
CDER	975	2.06	2,014	10	20,140
CBER	127	1.99	253	10	2,530
Total					22,670
Information Packages:					
CDER	756	1.84	1,394	18	25,092
CBER	112	1.81	203	18	3,654
Total					28,746
Grand Total					51,416

Dated: July 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17557 Filed 7–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 August 8, 2012, 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: Yvette Waples, 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: *ACPS-CP@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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: During the first session, the committee will discuss the uses and limitations of in vitro dissolution testing and propose future direction for evaluation including possible research. During the second session, the committee will receive an update on the FDA's recently posted draft guidances for industry on biosimilar products. This will be an awareness topic and there will not be formal Committee discussion or recommendation.

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 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 1, 2012. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 noon for the first session, and 3:45 p.m. to 4:15 p.m. for the second session. 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 July 24, 2012. 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