Prescribing Information.'' Highlights provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 remain subject to labeling requirements at § 201.80 (in the final rule, former § 201.57 was redesignated as § 201.80). Section 201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

B. Estimates of Reporting Burden

The PRA information collection analysis in the final rule (71 FR 3964–3967) (currently approved under OMB control number 0910–0572) estimated the reporting burden for a multiyear period. We are requesting that OMB extend approval for the information in this collection, as described below that will continue to be submitted to FDA during this multiyear period.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57) (Table 1)

New drug product applicants must: (1) Design and create prescription drug labeling containing Highlights, Contents, and FPI, (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval. Based on the projected data estimated in the final rule, FDA estimates that it takes applicants approximately 3,349 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or a BLA under the revised regulations. Approximately 84 applicants submit approximately 105 new applications (NDAs and BLAs) to FDA per year, totaling 351,645 hours.

In the **Federal Register** of December 19, 2011 (76 FR 78668), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

TABLE 1—ESTIMATED REPORTING BURDEN FOR NEW DRUG APPLICATIONS [1]

Category (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Burden for Labeling Requirements in §§ 201.56 and 201.57	84	1.25	105	3,349	351,645
Total					351,645

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6693 Filed 3–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0247]

Agency Information Collection Activities: Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

DATES: Submit either electronic or written comments on the collection of information by May 21, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information,

before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for 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 of 1997 (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: FDA Form 1571—OMB control number 0910–0014 and FDA Form 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)).

1. 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.

2. 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. As a result, FDA is submitting for OMB approval these additional estimates.

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: March 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6691 Filed 3–19–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0248]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal dispute resolution.

DATES: Submit either electronic or written comments on the collection of information by May 21, 2012.