SUPPORTING STATEMENT

Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products

(OMB Control Number 0910-0429)

A. Justification

1. Circumstances of Information Collection

This information collection approval request is for a 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 (the Modernization Act), 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 No.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 No. 0910-0014, and FDA Form 356h - OMB Control No. 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)).

2. Purpose and Use of Information

The agency is recommending the above procedures for submitting a meeting request 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 data bases. Use of the information in the agency's tracking data bases 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. 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.

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3. Use of Improved Information Technology

FDA has issued several guidances for industry to improve the use of information technology in the submission of marketing applications for human drugs and related reports. These guidance documents are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

4. Efforts to Identify Duplication

The information collection requested under the guidance does not duplicate any other information collection.

5. Involvement of Small Entities

Although new drug development is typically an activity completed by large multinational drug firms, the information collection requested under the guidance applies to small as well as large companies. Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences If Information Collected Less Frequently

As explained above, use of the meeting request information

in the agency's tracking data bases 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. 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. The information package will provide agency staff with 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.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

There is no inconsistency with the guidelines.

8. Consultation Outside the Agency

A 60-day notice was published in the Federal Register of November 13, 2008 (73 FR 67184) requesting comments on this information collection. No comments were received.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under these requirements.

10. Assurance of Confidentiality

Confidentiality of the information submitted under this guidance is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

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

A. Request For a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 907 sponsors and applicants (respondents) request approximately 2,210 formal meetings with CDER annually and approximately 144 respondents request approximately 287 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.

B. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 774 respondents submitted approximately 1,705 information packages to CDER annually and approximately 120 respondents submitted approximately 198 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 the Modernization Act, 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 No. 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.

Estimated Annual Reporting Burden

Meeting Requests and Information Packages	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
Meeting Requests					
CDER	907	2.44	2,210	10	22,110
CBER	144	1.99	287	10	2,870

Total					24,970
Information Packages					
CDER	774	2.20	1,705	18	30,690
CBER	120	1.65	198	18	3,564
Total					34,254
Grand Total					59,234

13. Estimates of Annualized Cost Burden to Respondents

FDA estimates an average industry wage rate of $50.00 per hour for preparing and submitting the information requested under the guidance. This figure is an average of the following wage rates (based on the percentage of time required for each type of employee): Upper management at $70.00 per hour; middle management at $35.00 per hour; and clerical assistance at $23.00 per hour. Using the averaged wage rate of $50.00 per hour, and multiplied times the total hour burden estimated above, the total cost burden to respondents is $2,961,200.

14. Estimates of Annualized Cost Burden to the Government

FDA estimates that there will be no additional costs associated with the receipt/review by FDA of the information

submitted under the guidance.

15. Changes In Burden

The change in burden is the result of submissions received under the guidance during the past 3 years, CDER and CBER received more formal meetings requests compared with 3 years ago.

16. Time Schedule, Publication, and Analysis Plans

There are no publications.

17. Displaying of OMB Expiration Date

The agency is not seeking to not display the expiration date for OMB approval of the information collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.