Guidance for Industry on Formal Meetings with Sponsors and Applicants
for PDUFA Products
0910-0429

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection approval request is for an 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;

- 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 the Information Collection

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 and Burden Reduction

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 and Use of Similar Information

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

5. Impact on Small Businesses or Other 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 of Collecting the Information 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. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of May 20, 2015 (80 FR 29010). FDA received no comments on the information collection.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

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.

A. Request For a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 1,099 sponsors and applicants (respondents) request approximately 2,366 formal meetings with CDER annually and approximately 175 respondents request approximately 264 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 959 respondents submitted approximately 1,901 information packages to CDER annually and approximately 142 respondents submitted

approximately 193 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.

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	1,099	2.15	2,366	10	23,660

CBER	175	1.51	264	10	2,640
Total					26,300
Information Packages					
CDER	959	1.99	1,901	18	34,218
CBER	142	1.36	193	18	3,474
Total					37,692
Grand Total					63,992

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

FDA estimates an average industry wage rate of $80.00 per hour for preparing and submitting the information requested under the guidance. Multiplied times the total hour burden estimated above, the total cost burden to respondents is $5,119,360.

14. Annualized Cost to the Federal 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. Explanation for Program Changes or Adjustments

We have adjusted the approved burden of 51,416 hours based on actual submissions received under the guidance during the past 3 years. The new burden is 63,992 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for the information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.