4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2434]

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, Agency, or we) 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@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 Products

OMB Control Number 0910-0429--Extension

This information collection supports the above captioned Agency guidance document. The guidance document was issued to help individuals with procedures on formal meetings between FDA and sponsors or applicants regarding the development and review of Prescription Drug User Fee Act (PDUFA) products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how FDA interprets and applies section 119(a) of the Food and Drug Administration Modernization Act of 2007 (Pub. L. 105-115), 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 collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests and 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 (iv)) and a "pre-NDA meeting" (§ 312.47(b)(2)). While the information collection provisions of § 312.47 are currently approved under OMB control number 0910-0014, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. The guidance document is available on our website at:

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf.

Request for a Meeting--Consistent with recommendations found in 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 application for the underlying product in accordance with our regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)). 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 IND submissions, and Form FDA 356h must accompany NDA and BLA submissions. These Agency forms are approved under OMB control numbers 0910-0014 and 0910-0338, respectively.

We recommend that a request be submitted in this manner to ensure that each request is kept in the administrative file with the complete application, and to ensure that pertinent information about the request is entered into appropriate tracking databases. Using information from our tracking databases enables us to monitor progress on activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that meeting requests include the following information:

- 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
- suggested dates and times for the meeting

We use the information to determine the purpose of the meeting, the necessary participants, the proposed agenda, and to schedule the meeting.

Information Package--The guidance also recommends that a sponsor or applicant submitting an information package provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or FDA. Information packages should 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)
- chemistry, manufacturing, and controls information that may be discussed (as appropriate)

The information package enables Agency staff to prepare for the meeting and allows appropriate time for reviewing relevant product data. Although FDA reviews similar

information in the meeting request, the information package should provide updated data reflecting the most current and accurate information available to the sponsor or applicant.

In the *Federal Register* of July 11, 2018 (83 FR 32130), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

Guidance Recommendations	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Meeting Requests:					
CDER	1,319	2.31	3,058	10	30,580
CBER	301	1.21	363	10	3,630
Subtotal					34,210
Information Packages:					
CDER	1,149	2.19	2,522	18	45,396
CBER	187	1.12	210	18	3,780
Subtotal					49,176
Total					83,386

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

Our estimated burden for the information collection reflects an overall increase since the previous OMB approval. We attribute this adjustment to an increase in the number of meeting requests and information packages received over the last few years.

Based on Agency data, we estimate 1,319 sponsors and applicants (respondents) request 3,058 formal meetings with CDER annually, and 301 respondents request 363 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 spends preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be 10 hours. We expect it takes this amount of time to gather and copy brief statements about the product as well as a description of the purpose and details of the meeting.

Also consistent with Agency data, we estimate 1,149 respondents submitted 2,522 information packages to CDER annually, and 187 respondents submitted 210 information packages to CBER annually, prior to a formal meeting regarding the development and review of a PDUFA product. We estimate 18 hours is needed to prepare the information package in accordance with the guidance.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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