4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0313]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

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 [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 All comments should be identified with the OMB control number 0910-NEW and title, "Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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. Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development--(OMB Control Number 0910-NEW)

FDA is issuing a draft guidance on the procedures for requesting meetings with Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, Humanitarian Use Device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. The draft guidance describes procedures for requesting, scheduling, conducting, and documenting such meetings.

The draft guidance describes three collections of information: (1) The submission of a meeting request (for informal and formal meetings), (2) the submission of a meeting package (for

formal meetings), and (3) the submission of draft meeting minutes (for formal and certain informal meetings). These collections of information will be used by the Agency to schedule and prepare for meetings on the issues described previously in this document and will provide for more productive meetings with stakeholders. This draft guidance refers to previously approved collections of information found in FDA regulations. Agency regulations at part 316

(21 CFR part 316) describe information that should be submitted in support of an orphan drug designation

request. The information collection provisions of part 316 have been approved under OMB control number 0910-0167. Agency regulations at § 814.102 (21 CFR 814.102) describe information that should be submitted in support of a HUD designation request.

The information collection provisions of § 814.102 have been approved under OMB control number 0910-0332.

A. Request for a Meeting

Under the draft guidance, a stakeholder interested in meeting with OOPD should submit a meeting request:

• For specific designation requests or grant applications, by emailing the identified point of contact for the designation request or grant application with the subject heading "Meeting Request"; or

• For other issues, by emailing the general OOPD inbox at orphan@fda.hhs.gov with the subject heading "Meeting Request" or by emailing the point of contact for each OOPD Program Area listed in the "Contact FDA" section of the OOPD's Web site (http://www.fda.gov/orphan), again with the subject heading "Meeting Request." In the draft guidance, FDA recommends that the meeting request, at a minimum, include (1) a brief statement of the meeting purpose, (2) whether the stakeholder prefers an informal or formal meeting, (3) suggested dates and times for the meeting, (4) preferred format of the meeting, and (5) the email address(es) to which OOPD should send a response to the meeting request (if different from the email address from which the request was sent) and telephone number for the primary contact for the stakeholder. Before scheduling a meeting, OOPD may ask the stakeholder for more information about the proposed

meeting to help determine whether an informal or formal meeting is most appropriate and who from OOPD should attend. For informal meetings, the information in the meeting request may suffice, although OOPD may ask for supplemental information via email or telephone.

B. Meeting Package

If a formal meeting is scheduled, FDA recommends that stakeholders submit a meeting package to OOPD at least 2 weeks before the meeting. Stakeholders are encouraged to submit the package electronically by email to the OOPD program contact who scheduled the meeting. In the draft guidance, FDA recommends that the meeting package contain the following information: (1) The date, time, and subject of the meeting; (2) an explanation of the meeting purposes; (3) basic information about the product to be discussed (e.g., product name or identifier, designation or application number (if applicable), proposed rare disease or condition, brief background about the product); (4) proposed meeting agenda; (5) any data, information, or presentation materials to support the discussion (if needed); and (6) a list of all individuals, with their titles and affiliations, who are expected to participate in the meeting on behalf of the stakeholder.

C. Draft Meeting Minutes

Under the draft guidance, a stakeholder should prepare a draft of summary meeting minutes for all formal meetings and certain informal meetings. These draft minutes should be sent to the OOPD program contact by email with the subject heading "Draft Meeting Minutes." The draft minutes should summarize the meeting discussion points, agreements, disagreements, and action items. OOPD will review and provide any revisions to the draft meeting minutes via email, and the stakeholder will then either accept the version as final and notify OOPD to that effect or will follow-up with questions and/or further revisions.

Description of Respondents: Individuals from industry, researchers, patient groups, and other stakeholders who seek a meeting with OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Burden estimate: Table 1 of this document provides an estimate of the annual reporting burden for the preparation and submission of meeting requests, meeting packages, and meeting minutes under the guidance.

Request for a meeting: Based upon information collected from OOPD program areas, approximately 2,120 informal and 46 formal meetings were requested with OOPD in fiscal year (FY) 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of meeting requests and stakeholders will remain the same or will only slightly increase, and therefore estimates the total number of meeting requests will be 2,166 annually (2120 informal and 46 formal meetings). The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the information to be submitted with a meeting request in accordance with the draft guidance, is estimated to be approximately 3 hours for informal meetings and approximately 10 hours for formal meetings. Based on FDA's experience, the Agency expects that it will take stakeholders this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting. Therefore, the Agency estimates that stakeholders will spend 6,820 hours per year (6,360 hours for informal meetings and 460 hours for formal meetings) preparing

meeting requests to OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Meeting package: Based upon information collected from OOPD program areas, OOPD held approximately 46 formal meetings in FY 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of formal meetings, and therefore meeting packages, may increase only slightly as a result of this guidance; thus, the Agency estimates that the total responses will be 46 annually. As stated previously, it is current practice for stakeholders to submit meeting packages to the Agency in advance of any such formal meeting. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the meeting package in accordance with this draft guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to gather and copy brief statements about the product, a description of details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency. Therefore, the Agency estimates that stakeholders will spend 828 hours per year submitting meeting packages to the Agency prior to a formal meeting regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Draft meeting minutes: Based upon information collected from OOPD program areas, OOPD received approximately 46 draft meeting minutes for formal meetings and 21 draft meeting minutes for informal meetings in FY 2013 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of stakeholders submitting draft meeting minutes may remain the same or increase only slightly; thus, the Agency estimates that the total number of respondents will be 67 annually. As stated previously, it is current practice for stakeholders to submit draft meeting minutes to the Agency after all formal meetings and certain informal meetings. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing draft meeting minutes in accordance with this draft guidance, is estimated to be approximately 8 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to summarize the meeting discussion points, agreements, disagreements, and action items. Therefore, the Agency estimates that stakeholders will spend 536 hours per year submitting draft meeting minutes to the Agency documenting the meeting outcomes, agreements, disagreements, and action items as follow-up to all formal and certain informal meetings.

In the Federal Register of April 9, 2014 (79 FR 19623), 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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Meeting Requests (informal)	2120	1	2120	3	6360
Meeting Requests (formal)	46	1	46	10	460
Meeting Packages	46	1	46	18	828
Meeting Minutes	67	1	67	8	536
Total					8,184

Dated: December 11, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-29612 Filed 12/17/2014 at 8:45 am; Publication Date: 12/18/2014]