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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development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 January 20, 2015.

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to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title, ''Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development.''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 Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development—(OMB Control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FDA is issuing a draft guidance on the procedures for requesting meetings with the Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests,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 The draft guidance describes procedures for requesting, scheduling, conducting, and documenting such meetings.

The draft guidance describes three collections of information: (1) The submission of a meeting request (for informal and formal meetings), (2) the submission of a meeting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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0097]

Providing Regulatory Submissions in Electronic Format—Standardized Study Data; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data.'' The guidance announced in this document is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that certain submissions under the FD&C Act and Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of final guidance on that topic. The guidance describes how FDA plans to implement the requirements for the electronic submission of standardized study data contained in certain submissions under new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs). This finalizes the revised draft guidance that was issued on February 6, 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, rm. 7301, Silver Spring, MD 20993, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDASIA (Pub. L. 112–144), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A, entitled ''Electronic Format for Submissions.'' Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under sections 351(a) or (k) of the PHS Act (42 U.S. C. 262(a) or (k)) be submitted to FDA in electronic format no earlier than 24 months after FDA issues final guidance on that topic.

In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this guidance, announcing its determination that the study data contained in the submission types identified in this guidance must be submitted electronically (except for submissions that are exempted), in a format that FDA can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions of study data that use the standards, formats, and terminologies specified in the Data Standards Catalog [1] posted to the FDA's Study Data Standards Resources Web page.

In the **Federal Register** of February 6, 2014 (79 FR 7201), FDA announced the availability of the revised draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data.'' The comment period on the revised draft guidance ended on May 6, 2014. We reviewed all comments received on the draft guidance and revised several sections of the guidance. The updates include:

Section II.A: (1) Clarified which INDs and BLAs are addressed in this guidance. Specifically, a footnote was added to clarify the meaning of ''certain'' in the context of BLAs and INDs and states that the guidance is not applicable to INDs for devices that are regulated by CBER as biological products under section 351 of the PHS Act and to INDs that are noncommercial. Further, the guidance is not applicable to those devices that are regulated by CBER as biological products under section 351 of the PHS Act. Examples are provided in this regard. (2) Clarified that both clinical and nonclinical study data are within the scope of the guidance.

Section II.C: (1) Clarified that the Agency may refuse to file an NDA or BLA or refuse to receive an ANDA containing study data that are not in conformance with the required standards. (2) Clarified that both the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Standard Exchange for Nonclinical Data (SEND) are examples of study data standards for tabulations data. (3) Clarified that some controlled terminologies are extensible and permit additions to existing code lists. It is the expectation that sponsors or applicants will use the controlled terminologies maintained by external organizations as the standard.

Section II.D: Clarified the waiver process.

Section II.E: (1) Clarified that FDA recognizes that version updates to standards may be released in the interval between the start of a study and the submission of study data to the Agency and the Data Standards Catalog may list more than one version of a supported standard. (2) Specified the definition of study start date for both clinical and nonclinical studies. (3) Revised terminology to more clearly state when a particular requirement becomes required.

This guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act by specifying the format for electronic submission of study data contained in NDA, ANDA, BLA, and IND submissions. With the publication of this **Federal Register** notice of availability, all studies with a start date [2] 24 months or later after the

[1] Available at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

[2] For purposes of this guidance, the study start date for clinical studies is the earliest date of informed consent among any subject that enrolled in the study. For example, see Study Start Date (also known as the study initiation date) in the SDTM Trial Summary Domain (TSPARMCD = SSTDTC). For nonclinical studies, the study start date is the date on which the study protocol or plan is