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 This finalizes the revised draft guidance that was issued on February 6, 2014.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

Federal Register notice must use the appropriate FDA-supported standards, formats, and terminologies specified in the Data Standards Catalog for NDA, ANDA, and certain BLA submissions. Study data contained in certain IND submissions must use the specified formats for electronic submission in studies with a start date 36 months or later after this **Federal Register** notice of availability.

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. Because this guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words must or required, it is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, and INDs. The information collection discussed in the guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been voluntarily submitting standardized study data in electronic format. Under FDASIA, sponsors and applicants will be required to make all of these submissions electronically in compliance with the specified standards, formats, and terminologies. These requirements will be phased in over 2- and 3-year periods after the issuance of this guidance.

For many years sponsors and applicants have been submitting electronically using the electronic common technical document format and have included electronic study data in both legacy and standardized formats. For some sponsors and applicants there may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and this guidance, because some sponsors and applicants would have to change from submissions that have included legacy (non-standard) study data to submissions in compliance with this guidance. FDA estimates that for some sponsors and applicants the costs may be as follows:

- *Data management (hardware/software):* $350,000–$1,000,000
- *Initial data management operations:* $500,000–$1,000,000
- *Training:* $100,000—$250,000

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: December 12, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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approved (signed) by the Study Director. For example, see Study Start Date in the SEND Trial Summary Domain (TSPARMCD = STSTDTC), *http://www.cdisc.org.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0085]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

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 0910–0629. 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.

Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics—(OMB Control Number 0910–0629)—Extension

The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance addresses several types of manufacturing arrangements (*i.e.,* short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities; (2) notification of results of tests and investigations regarding or possibly impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.