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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0097]

Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Standardized Study Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data." The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal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 The draft guidance describes how FDA plans to implement the requirements for the electronic submission of standardized study data contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) and is being issued for public comment. This document supersedes the guidance entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" that was issued in February 2012.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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 draft 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. 1160, Silver Spring, MD 20993, ronald.fitzmartin@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

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 draft guidance, announcing its determination that the study data contained in the submission types identified in this draft 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 Study Data Standards Catalog[1] posted to FDA's Study Data Standards Resources Web page.

This revised draft guidance on standardized study data will supersede the draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" that was issued in February 2012. When finalized, 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. After publication of the Federal Register notice of availability of the final

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

guidance, all studies with a start date[2] 24 months after the 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 after the 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 draft 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 draft 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 draft 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 draft 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.

[2] For purposes of this guidance, the study start date is the earliest date of informed consent among any subject that enrolled in the study. For example, see Study Start Date in the SDTM Trial Summary Domain (TSPARMCD = SSTDTC), http://www.cdisc.org.

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 the final 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 the final 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 the final 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: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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