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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1953]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act; 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--Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act." The guidance announced in this notice sets forth FDA's interpretation of the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that certain submissions under the FD&C Act and the Public Health Service Act be submitted in electronic format, beginning no earlier than 24 months after issuance of a final version of a guidance document specifying the format for such electronic submissions. This guidance describes how FDA interprets and plans to implement the electronic submission requirements and finalizes the draft guidance that was issued on February 6, 2014.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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research

(CBER), Food and Drug Administration, 10903 New Hampshire Avenue, 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 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act." Section 1136 of 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" (21 U.S.C. 379k-1). Drug and biological product submissions are addressed in section 745A(a) of the FD&C Act.

Section 745A(a)(1) of the FD&C Act describes the general scope of section 745A(a) and provides that submissions under new drug applications (NDAs), abbreviated new drug

applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) must be in electronic format specified in FDA guidance. Section 745A(a)(2) of the FD&C Act states that the guidance issued by FDA may provide a timetable for future standards and criteria for waivers and exemptions. Section 745A(a)(3) of the FD&C Act provides that the electronic submission requirements in section 745A(a) do not apply to submissions under section 561 of the FD&C Act (21 U.S.C.360bbb).

This guidance describes FDA's interpretation of the scope of section 745A(a) of the FD&C Act. It announces that certain INDs will be exempted from the electronic submission requirements. Finally, it describes the process and timetable that FDA will use to implement the electronic submission requirements. As described in the guidance, FDA will develop individual guidances to specify the electronic formats for certain types of submissions under section 745A(a). Under section 745A(a)(1) of the FD&C Act, electronic submissions can be required no earlier than 24 months after FDA issues a final guidance. Therefore, no earlier than 24 months after issuance of the final version of an individual guidance specifying the format for certain types of submissions under section 745A(a) of the FD&C Act, the Agency will begin requiring that the submissions under NDAs, ANDAs, certain BLAs, and certain INDs be submitted in the specified electronic format for the types of submissions described in that guidance.

Individual guidances will be developed to specify the electronic formats, subject matter, and scope of applicability for certain submissions under section 745A(a) of the FD&C Act. Once an individual guidance is finalized and the timetable for implementation described in that guidance has passed, the guidance will have binding effect and the electronic format(s) specified in that guidance must be used for submissions to NDAs, ANDAs, certain BLAs, and certain INDs.

In the Federal Register of February 6, 2014 (79 FR 7200), FDA announced a draft version of this guidance entitled "Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act." The comment period on the 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 III.A and III.B: Clarified that the scope of the requirement under section 754A(a) does not extend to certain INDs and certain BLAs. Also clarified that certain INDs are exempted from the electronic submission requirements under section 745A(a)(2). Specifically, we clarified that INDs and BLAs for devices that are regulated by CBER as biological products under Section 351 of the Public Health Service (PHS) Act are instead subject to the requirements under Section 745A(b), and that, issued in section 745A(a)(2), INDs that are noncommercial are exempt from the requirements under section 745A(a). We provided examples in this regard.

Section III.D: Clarified that the individual guidances under 745A(a) will specify electronic formats, subject matter, and scope of applicability, as well as the timetable for implementation.

Section III.F: Clarified the timetable under which revisions or updates to electronic submission standards will take effect.

FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because this guidance contains binding provisions. In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to specify in guidance the format for the electronic submissions required under that section. Accordingly, this guidance explains such requirements under section 745A(a)

of the FD&C Act, indicated by the use of the words must or required, and therefore 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

This guidance contains no collection of information. As discussed in the guidance, FDA intends to develop individual guidances to specify the electronic formats for certain submissions under section 745A(a) of the FD&C Act. We will discuss any information collection subject to clearance by OMB under the Paperwork Reduction Act in each Federal Register notice announcing the availability of the individual guidances that specify the required electronic formats.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments 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 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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