DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1006]

Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; 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—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications.'' The guidance 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 outlines Electronic Common Technical Document (eCTD) specification requirements for submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs).

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 (CDER), 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: Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993, email: *virginia.hussong@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

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 (21 U.S.C. 379k–1), 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 submission types identified in this guidance must be submitted electronically (except for submissions that are exempted) in the format specified in this guidance.

This guidance (and the technical specification documents it incorporates by reference) describes how submissions under section 745A(a) of the FD&C Act must be organized and submitted in electronic format using eCTD specifications listed in the FDA Data Standards Catalog (*http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*). For more information concerning how the FDA interprets section 745A(a), see the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section745A(a) of the Federal Food, Drug, and Cosmetic Act'' (available at *http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/default.htm*). The eCTD is an International Conference on Harmonization (ICH) format based on specifications developed by ICH and its member parties. FDA's CDER and CBER have been receiving submissions in the eCTD format since 2003, and eCTD has been the recommended format for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format.

This guidance finalizes and replaces the previous 2013 draft guidance on eCTD specifications. This supersedes the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' that was issued in June 2008. This guidance is applicable to all submissions within the scope of section 745A(a) of the FD&C Act, *i.e.,* NDAs, ANDAs, certain BLAs, and certain INDs and all subsequent submissions, including amendments, supplements, and reports, to these submission types. This guidance is not applicable to submissions for blood and blood components, including Source Plasma.

In the **Federal Register** of July 25, 2014 (79 FR 43494), FDA announced the availability of the revised draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications.'' The comment period on the revised draft guidance ended on September 23, 2014. We reviewed all comments received on the draft guidance and revised several sections of the guidance. The updates include:

Section I: Clarified that in addition to this guidance and existing technical specifications, more detailed technical instructions will be issued in the form of a technical conformance guide.

Section III.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 FDA considers master files to be submissions to an NDA, ANDA, BLA, or IND, and therefore to fall within the scope of requirements set forth in section 745A(a). These include new drug master files (DMFs) (21 CFR 314.420), new biological product files (BPFs) (21 CFR

601.51), and any amendments to or annual reports on previously submitted DMFs or BPFs. This guidance also applies to submissions for drug/device combination products filed pursuant to section 505 of the FD&C Act or subsection (a) or (k) of section 351 of the PHS Act.

Section Technical Specification Documents Incorporated by Reference: Provides a list of documents incorporated by reference into this guidance and provides a complete listing of technical supportive files on the FDA eCTD Web page at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.*

We also received a comment concerning the implementation timeline for the Portable Document Format (PDF) technical specification. As discussed in the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act,'' certain technical specifications are required no earlier than 2 years after the final guidance is published.

This guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act by specifying the format for electronic submissions. All submissions submitted 24 months after the publication of this guidance must use the appropriate FDA-supported eCTD specifications for NDA, ANDA, and certain BLA submissions. Certain IND submissions must use the FDA-supported eCTD specifications for electronic submissions submitted 36 months after publication of this guidance.

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

This 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, INDs, master files, and advertising and promotional labeling. 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 submitting NDAs, ANDAs, BLAs, INDs, and master files electronically since 2003, and the majority of these submissions are already received in electronic format. Under section 745A(a) of the FD&C Act, sponsors and applicants are required to file most of these submissions electronically. These requirements will be phased in over 2- and 3-year periods after the issuance of this guidance.

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 may have to upgrade eCTD specifications and/or change their method of submitting information to FDA. FDA estimates that, for some sponsors and applicants, the costs may be as follows:

- eCTD Publishing Software: $25,000 to $150,000
- Publishing Operations Support: $50,000 to $1 million
- Training: $5,000 to $50,000

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 *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1245]

Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Draft 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 draft guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.'' This guidance provides recommendations for sponsors of investigational new drug applications (INDs), and applicants that submit new drug applications, abbreviated new drug applications (ANDAs), and supplements to these applications for immediate-release (IR) solid oral dosage forms, and who wish to request a waiver of in vivo bioavailability (BA) and/or bioequivalence (BE) studies.

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 July 6, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.