



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1256]

Draft Revision of Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format-- Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.” The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA) which amended the Federal Food,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Act) be submitted in electronic format, beginning no earlier than 2 years after publication of the final version of the draft guidance. The draft guidance describes how FDA plans to implement the requirements for the electronic submission of applications for certain human pharmaceutical products and is being issued for public comment. In its final form, this document will also supersede the guidance titled “Guidance for Industry Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” that was issued in October 2005 and revised in April 2006 and June 2008.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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:

Virginia Hussong,
Center for Drug Evaluation and Research,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 22, rm. 1161,
Silver Spring, MD 20993,

email: virginia.hussong@fda.hhs.gov;

or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852,

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

The electronic Common Technical Document (eCTD) is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the 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.

FDASIA (Public Law 112-144, 126 Stat. 993 (2012)), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A, titled "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, and submissions under sections 351(a) or (k) of the PHS Act, be submitted to FDA in electronic format no earlier than 24 months after FDA issues the final guidance described in this section.

In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that 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 made using the eCTD version 3.2.2 specifications. Requirements for electronic submission will be phased in according to the following schedule: (1) 24 months after publication of the final version of this draft revised guidance, the requirements will apply to new drug application (NDA), abbreviated new drug application (ANDA), and biologics license application (BLA) submissions and (2) 36 months after publication of the final guidance, the requirements will apply to investigational new drug application (IND) submissions. Section 745A(a) of the FD&C Act does not apply to master files and advertising and promotional labeling submissions. However, FDA accepts and strongly encourages the submission of master files and advertising and promotional labeling materials electronically, as described in the draft guidance.

In Section 745A(a), Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. To the extent that the 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 (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

At the same time, the draft guidance also provides guidance on FDA's interpretation of the statutory electronic submission requirement and the Agency's current thinking on the best

means for implementing other aspects of the electronic submission program. Therefore, to the extent that the draft guidance includes provisions that are not part of the requirements under section 745A(a), it is being issued in accordance with FDA's GGP regulation (21 CFR 10.115). Such parts of the draft guidance, when finalized, will represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach for these recommendations if such an approach would satisfy the requirements of the applicable statutes and regulations. The use of the word should in the draft guidance means that something is suggested or recommended, but not required. Accordingly, the final guidance will contain both binding and nonbinding provisions.

II. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (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, INDs, master files, and advertising and promotional labeling. 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.

Sponsors and applicants have been submitting NDAs, ANDAs, BLAs, and INDs electronically since 2003, and the majority of these submissions are already received in electronic format. Under FDASIA, sponsors and applicants will be required to make all of these

submissions electronically. These requirements will be phased in over 2 and 3 year periods after the issuance of the final guidance.

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 convert from paper-based submissions to electronic submissions. In accordance with the PRA, prior to publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any costs that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

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/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Persons with access to the Internet may obtain the document at either

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Dated: December 27, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

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