



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Providing Regulatory Submissions in Electronic Format--Submission of Manufacturing Establishment Information; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Submission of Manufacturing Establishment Information." This guidance discusses the requirements for a valid electronic submission of manufacturing establishment information (MEI) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This action will streamline the review of all manufacturing establishments involved in the preparation of a drug or biological product by consolidating information in one location and eliminating the inclusion of erroneous and/or outdated information from other Agency files.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-1953 for "Providing Regulatory Submissions in Electronic Format--Submission of Manufacturing Establishment Information." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993. 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.

FOR FURTHER INFORMATION CONTACT: Regarding drug products: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4244, Silver Spring, MD 20993-0002, 301-796-3191.

Regarding biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Submission of Manufacturing Establishment Information."

This draft guidance discusses the requirements and implementation of section 745A(a) of the FD&C Act (21 U.S.C. 379k-1) regarding valid electronic submissions of MEI. Twenty-four months after this draft has been finalized, MEI contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and amendments, supplements, or resubmissions of these application types must be submitted electronically in the format specified in this guidance. This draft guidance also applies to drug master files that are submitted for incorporation by reference into an NDA, ANDA, or BLA.

Under current regulations at 21 CFR 314.50(d) and 21 CFR 601.2(a), applicants and holders of approved applications are required to submit contact information for each manufacturing establishment involved in the manufacture of the drug or biological product, as well as other information relating to the manufacture of the product. This information is part of the existing application form (FDA Form 356h, "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use"). We have found that the MEI is sometimes incomplete, and scattered throughout electronic submissions. This can lead to delays in application processing.

The Agency is requiring that applicants submit a single, consolidated list of information about each manufacturing establishment mentioned in any application. This information must include the name and address of each manufacturing establishment involved in the manufacture of the drug or biological product, specific information regarding the physical location of the

establishment, facility identifiers assigned to the establishment by FDA, contact information for the person responsible for scheduling inspections at the establishment, and the specific manufacturing operations conducted at the establishment.

We believe the required electronic MEI can be consolidated to appear in a single location to facilitate the complete, timely, and accurate review of all manufacturing establishments involved in the preparation of a drug or biological product. This will help to eliminate the inclusion and/or maintenance of potentially outdated and erroneous information that could be retrieved from other Agency files and will enable proper identification and timely evaluation of manufacturing establishments for conformance with requirements, including current good manufacturing practices.

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 draft guidance discusses the electronic submission of MEI contained in an NDA, ANDA, or BLA to the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research by specifying the format for the electronic submission of such submissions. The information collection discussed in the guidance is contained in our NDA and ANDA regulations (part 314) and approved under OMB control number 0910-0001, and our BLA regulations (part 601) and approved under OMB control number 0910-0338. Currently, MEI is submitted as part of the existing application form, Form FDA 356h, and is approved by OMB under control number 0910-0338.

III. 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/default.htm>, or <https://www.regulations.gov>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31626 Filed: 12/28/2016 8:45 am; Publication Date: 12/29/2016]