



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1288]

Electronic Submission of Lot Distribution Reports; 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 document entitled "Electronic Submission of Lot Distribution Reports; Guidance for Industry." The guidance document provides information and recommendations pertaining to the electronic submission of lot distribution reports for applicants with approved biologics license applications (BLAs). FDA recently published in the Federal Register a final rule requiring that, among other things, lot distribution reports be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Electronic Submission of Lot Distribution Reports" dated August 2014, and is intended to help licensed manufacturers of products distributed under an approved BLA (henceforth referred to as applicants) comply with the final rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bld. 71, rm. 3128, Silver

Spring, MD 20993-0002 or 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. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Jared Lantzy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1116, Silver Spring, MD 20993, email: esub@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Electronic Submission of Lot Distribution Reports; Guidance for Industry." The guidance provides information and recommendations pertaining to the electronic submission of lot distribution reports. The guidance provides information on how to electronically submit lot distribution reports for biological products under approved BLAs for which CBER or CDER has regulatory responsibility. The guidance does not apply to any other biological product.

FDA published in the Federal Register of June 10, 2014 (79 FR 33072), a final rule requiring electronic submission of certain postmarketing submissions. Among other things, under this rule applicants are required to submit biological lot distribution reports to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help applicants subject to lot distribution reporting comply with the final rule. Along with other information, the guidance provides updated information about the following: (1) Structured Product Labeling standard and vocabulary for electronic submission of lot distribution reporting; (2) additional resources such as implementation guide, validation procedures and links with further information; and (3) procedures for requesting temporary waivers from the electronic submission requirement.

In the Federal Register of August 29, 2014 (79 FR 51576), FDA announced the availability of the draft guidance entitled " Guidance for Industry: Electronic Submission of Lot Distribution Reports" dated August 2014. FDA published a correction notice to correct the docket number in the Federal Register of September 16, 2014 (79 FR 55497). FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. FDA is finalizing the draft guidance with only editorial changes. The guidance announced in this notice finalizes the draft guidance dated August 2014.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR 600.81 and 600.90 have been approved under 0910-0308.

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 guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-06498 Filed: 3/20/2015 08:45 am; Publication Date: 3/23/2015]