4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-S-0009]

Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Electronic Submission of Lot Distribution Reports" dated August 2014. The draft guidance document provides information and recommendations pertaining to the electronic submission of lot distribution reports for applicants with approved biologics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 The draft guidance, when finalized, is intended to help licensed manufacturers of products distributed under approved BLAs (henceforth referred to as applicants) comply with the final rule.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research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 or 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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800 or CDER at 301-796-3400. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: 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 (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1116, Silver Spring, MD 20993-0002, email: esub@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Electronic Submission of Lot Distribution Reports" dated August 2014. The draft guidance provides information and recommendations pertaining to the electronic submission of lot distribution reports. The draft 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. When finalized, this guidance will not apply to any other biological product.

FDA recently 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 draft guidance, when finalized, is intended to help applicants subject to lot distribution reporting comply with the final rule. Along with other information, the draft 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.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 OMB control number 0910-0308.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft 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: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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