4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0362]

Draft Guidance for Industry and Food and Drug Administration Staff; Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization Standard 11040-4; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry and FDA staff entitled "Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4." These supplemental data are necessary for FDA to ensure the safe and effective use of glass syringes that comply with the ISO 11040-4 standard when connected to devices ("connecting devices") that comply with the ISO 594-2 standard.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single printed copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129; Silver Spring, MD 20993. Send one self-addressed adhesive label to assist

the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301-796-8930. See the SUPPLEMENTARY INFORMATION section for electronic access to the 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4." This document provides guidance to sponsors seeking to rely on conformity to ISO Standard 11040-4 in submissions for glass syringes products. FDA has become aware of adverse events and product quality events related to connectivity problems when certain glass syringes are used with connecting devices, including connecting devices to conform to the FDA-recognized ISO 594-2 standard. Accordingly, FDA has determined that, for glass syringes, demonstrating conformity

to the ISO 11040-4 standard alone does not ensure that the glass syringe can be properly connected to connecting devices. Therefore, this guidance document identifies additional, technical information that should be included in an investigational device exemption (IDE), humanitarian device exemption (HDE), 510(k), or postmarket application (PMA) for a glass syringe product, or in an investigational new drug application (IND), a biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA) for a drug or biological product that is delivered with such a glass syringe product, to demonstrate that the glass syringe can be properly connected to connecting devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4." 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. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

IV. 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 part 314 for NDAs have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 814 subpart B for PMAs have been approved under OMB control number 0910-0231. The collections of information in FD&C Act subpart E for 510(k) notifications have been approved under OMB control number 0901-0120.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07685 Filed 04/02/2013 at 8:45 am; Publication Date: 04/03/2013]