VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. The FDA guidance entitled ''Draft Guidance for Industry and FDA Staff: Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions,'' available at *http://www.fda.gov/medicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm.*

Dated: *November 25, 2014.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28267 Filed 12–1–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0295]

Guidance for Industry on Scale-Up Post-Approval Changes: Manufacturing Equipment Addendum; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a scale-up and post-approval changes (SUPAC) guidance for industry entitled ''SUPAC: Manufacturing Equipment Addendum.'' This replaces the draft guidance of the same name that combined and superseded ''SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms: Manufacturing Equipment Addendum,'' published on January 1, 1999; and ''SUPAC–SS: Nonsterile Semisolid Dosage Forms; Manufacturing Equipment Addendum,'' published as a draft on December 1, 1998. FDA revised the draft manufacturing equipment addenda to remove the equipment examples and to clarify the types of processes being referenced.

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 Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 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: Akm Khairuzzaman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3886.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a SUPAC guidance for industry entitled ''SUPAC: Manufacturing Equipment Addendum.'' This guidance replaces the draft guidance of the same name that superseded the following guidances for industry: (1) ''SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms: Manufacturing Equipment Addendum,'' published on January 1, 1999, and (2) ''SUPAC–SS: Nonsterile Semisolid Dosage Forms; Manufacturing Equipment Addendum, ''published as draft on December 1, 1998. When published, these guidances included tables that listed specific equipment that were misinterpreted as a list of FDA required equipment. In addition, FDA is concerned that the equipment addenda may no longer reflect current practices and may be limiting, instead of encouraging, manufacturers to continually evaluate and update practices. FDA has removed the tables listing specific manufacturing equipment from these guidances and combined them into a single addendum. FDA has also made some changes to clarify the types of processes being referenced.

This guidance should be used with the following guidances for industry to determine what documentation should be submitted to FDA regarding equipment changes: (1) ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation,'' (2) ''SUPAC–MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation,'' and (3) ''SUPAC–SS: Nonsterile Semisolid Dosage Forms, Scale-Up and Post Approval Changes: Chemistry Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation.''

As part of a greater effort, FDA is thoroughly reviewing the SUPAC guidance series to determine how these guidances fit with current manufacturing practices, including, but not limited to, risk-based assessment approaches and quality by design principles. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on manufacturing equipment. 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.*

Dated: *November 25, 2014.*

Leslie Kux,

Associate Commissioner for Policy.

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