4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0295]

Draft Guidance for Industry on Scale-Up and Post-Approval Changes: Manufacturing Equipment Addendum; Availability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The Food and Drug Administration (FDA) is announcing the availability of a scale-up and post-approval changes (SUPAC) draft guidance for industry entitled "SUPAC: Manufacturing Equipment Addendum." This revised draft document combines and supersedes "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 has now revised the draft manufacturing equipment addenda to remove the equipment examples and to clarify the types of processes being referenced.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance and on any other part of the SUPAC guidance series, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,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 that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a SUPAC draft guidance for industry entitled "SUPAC: Manufacturing Equipment Addendum." This revised draft document combines and supersedes 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" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070636.pdf), (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" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070640.pdf), 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" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070930.pdf).

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. These efforts will also be considered part of the finalization process for this guidance.

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 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: March 26, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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