4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0691]

Guidance on Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs." This guidance is intended to help manufacturers of PET drugs meet the requirements for the Agency's current good manufacturing practice regulations for PET drugs.

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

ADDRESSES: Submit written requests for single copies of this 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 request. 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:

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Bldg. 51, rm. 6164,

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs." Most PET drugs are designed for parenteral administration and are produced by aseptic processing. The goal of aseptic processing is to make a product that is free of microorganisms and toxic microbial byproducts, such as bacterial endotoxins. The media fill is the performance of an aseptic manufacturing procedure using a sterile microbiological growth medium in place of the drug solution to test whether the aseptic procedures are adequate to prevent contamination during actual drug production. This guidance takes the form of questions and answers written specifically to help manufacturers comply with the Agency's current good manufacturing practices for PET drugs (21 CFR part 212) regarding media fills.

A draft guidance of the same title was announced in the Federal Register on September 30, 2011 (76 FR 60847), and Docket No. FDA 2011-D-0691 was open for comments until December 29, 2011. We received comments from industry and professional societies. We have

carefully considered, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on media fills and process simulations for PET drugs. 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 to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

III. 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 part 212 have been approved under OMB control number 0910-0667.

IV. 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: April 6, 2012

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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