4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0852]

Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry." The guidance document provides sponsors of virus or bacteria-based gene therapy products (VBGT products) and oncolytic viruses or bacteria (oncolytic products) with recommendations on how to conduct shedding studies during preclinical and clinical development. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2014.

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 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. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-

800-835-4709 or 240-402-8010. 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: Tami Belouin, 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Guidance for Industry." The guidance provides sponsors of VBGT and oncolytic products with recommendations on how to conduct shedding studies during preclinical and clinical development. VBGT and oncolytic products are derived from infectious viruses or bacteria. In general, these product-based viruses and bacteria are not as infectious or as virulent as the parent strain of virus or bacterium. Nonetheless, FDA is issuing this guidance because the possibility that infectious product-based viruses and bacteria may be shed by a patient raises safety concerns related to the risk of transmission to untreated individuals. To understand the risk associated with product shedding, sponsors should collect data in the target patient population in clinical trials before licensure.

In the Federal Register of July 9, 2014 (79 FR 38908), FDA announced the availability of the draft guidance of the same title. FDA received a few comments on the draft guidance and

those comments were considered as the guidance was finalized. A summary of changes includes reorganization of and within certain sections of the guidance, and addition of new bullet points and information to address specific questions raised in the comments and at the November 6, 2014, meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2014.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on design and analysis of shedding studies for virus or bacteria-based gene therapy and oncolytic products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. 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 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 600 have been approved under OMB control number 0910-0308; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755.

III. 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.

IV. Electronic Access

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

Dated: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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