4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0663]

Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry" dated March 2015. The guidance document provides investigational new drug application (IND) sponsors and applicants for a biologics license application (BLA) or a supplement to a BLA (BLA supplement), with recommendations on considerations when assessing whether to submit an Environmental Assessment (EA) for gene therapies, vectored vaccines, and related recombinant viral or microbial products (GTVVs). The guidance also contains recommendations as to what information should be included in an EA and what you can expect once an EA is filed. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2014.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 240-402-7800. 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 "Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Guidance for Industry" dated March 2015. The guidance document provides IND sponsors and applicants for a BLA or a BLA supplement, with recommendations on considerations when assessing whether to submit an EA for GTVVs. The guidance also contains recommendations as to what information should be included in an EA and what you can expect once an EA is filed. The guidance supplements the guidance entitled "Guidance for Industry: Environmental Assessment of Human Drug and Biologics

Applications" dated July 1998 (July 27, 1998, 63 FR 40127) (1998 Guidance) and supersedes the recommendations for GTVVs in section IV.B.1 "Assessing Toxicity to Environmental Organisms" in the 1998 Guidance. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2014.

In the Federal Register of June 20, 2014 (79 FR 35361), FDA announced the availability of the draft guidance of the same title dated June 2014. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. There were no changes to the guidance except for one correction to a technical error regarding influenza taxonomy. The guidance announced in this notice finalizes the draft guidance dated June 2014.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. 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 25 have been approved under OMB control number 0910-0322; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information for 21 CFR part 601 have been approved under OMB control number 0910-0338.

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: March 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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