



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products" dated June 2014. The draft guidance document provides investigational new drug application (IND) sponsors and applicants for a biologics license application (BLA), or a supplement to a BLA, with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 sponsors and applicants can expect once an EA is filed. The guidance, when finalized, will supplement the guidance entitled "Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications," dated July 1998 (1998 Guidance) and will also supersede those recommendations for GTVVs in section IV.B.1 Assessing Toxicity to Environmental Organisms" of the guidance.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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: 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 draft document entitled "Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products" dated June 2014.

The draft guidance document provides IND sponsors and applicants for a BLA, or a supplement to a BLA, 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 sponsors and applicants can expect once an EA is filed. Products addressed in the guidance include all GTVVs, but not live-attenuated viral or microbial vaccines created by traditional methods such as serial passaging or recombinant protein-based vaccines. The guidance, when finalized, will supplement the 1998 Guidance, and will also supersede those recommendations for GTVVs in section IV.B.1 entitled "Assessing Toxicity to Environmental Organisms" of the guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.