4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0092]

Draft Guidance for Industry on Immunogenicity Assessment for Therapeutic Protein Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Immunogenicity Assessment for Therapeutic Protein Products." Therapeutic protein products may elicit immune responses, and these responses may lead to serious or life-threatening adverse events for the patient or loss of efficacy of the product. This draft guidance is intended to assist manufacturers to develop a risk-based approach in both the preclinical and clinical phases of the development of therapeutic protein products to evaluate and mitigate immune responses that may adversely affect their safety and efficacy.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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, or Office of

Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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

Amy Rosenberg,

Center for Drug Evaluation and Research,

Food and Drug Administration,

8800 Rockville Pike,

Bldg. 29A, rm. 2D-16,

Bethesda, MD 20892,

301-827-1790; or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852-1448,

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Immunogenicity Assessment for Therapeutic Protein Products." The purpose of this document is to assist manufacturers and clinical investigators involved in the development of therapeutic protein products for human use. The guidance outlines, and recommends adoption of, a risk-based approach to evaluating and mitigating the potential for immunogenicity that may affect the safety and efficacy of therapeutic protein products. The guidance describes various product- and patient-specific factors that can affect the immunogenicity of protein therapeutics and provides recommendations pertaining to each of these factors that may reduce the likelihood that these products will generate an immune response. In addition, the guidance offers a series of recommendations for risk mitigation in the clinical phase of development of protein therapeutics. The draft guidance also provides supplemental information on the diagnosis and management of particular adverse consequences of immune responses to protein therapeutics and contains brief discussions of the uses of animal studies and the conduct of comparative immunogenicity studies.

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 immunogenicity assessment of therapeutic protein products. 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 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: February 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03019 Filed 02/08/2013 at 8:45 am; Publication Date: 02/11/2013]