4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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 or the Agency) is announcing the availability of a guidance for industry entitled "Immunogenicity Assessment for Therapeutic Protein Products." Therapeutic protein products may elicit immune responses, which may lead to serious or life-threatening adverse events for the patient or loss of efficacy of the product. This guidance is intended to assist manufacturers and clinical investigators in developing a risk-based approach in both the nonclinical and clinical phases of product development that will allow them to evaluate and reduce the likelihood that the immunogenicity of the product will cause harm to patients. This guidance finalizes the draft guidance issued in February 2013.

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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 that office in processing your

requests. 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: Amy Rosenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 2238, Silver Spring, MD 20892, 240-402-9789; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 71, rm. 7301, Rockville, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Immunogenicity Assessment for Therapeutic Protein Products." The purpose of this guidance is to assist manufacturers and clinical investigators involved in the development of therapeutic protein products for human use in evaluating and reducing the risk of adverse events caused by immune responses to these products. The guidance: (1) Outlines and recommends adoption of a risk-based approach to evaluating and mitigating potential immune responses to therapeutic protein products that may affect their safety and efficacy, (2) describes various product- and patient-specific factors that affect the immunogenicity of or immune responses to therapeutic protein products and provides recommendations pertaining to each factor that may reduce the likelihood that an immune response will be generated to the product, (3) offers a series of recommendations for risk mitigation in the clinical phase of development of therapeutic protein products,

(4) provides supplemental information on the diagnosis and management of particular adverse consequences of immune responses to therapeutic protein products, and (5) discusses briefly the use of animal studies and the conduct of comparative immunogenicity studies.

In the Federal Register of February 11, 2013 (78 FR 9702), FDA announced the availability of the draft guidance of the same title dated February 2013. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

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 immunogenicity assessments for 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/Guidances/default.htm; or http://www.regulations.gov.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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