4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0234]

Draft Guidance for Industry on Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product." This guidance is intended to assist sponsors in developing a clinical pharmacology program to support a decision that a proposed therapeutic biological product is biosimilar to, that is not clinically meaningfully different from, its reference product. Specifically, the guidance discusses some of the overarching concepts related to clinical pharmacology studies for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. This draft guidance is one in a series of guidances that FDA is developing to implement the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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, Food and Drug Administration, 1401 Rockville Pike, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6340, Silver Spring, MD 20993-0002, 301-796-2500, email: sandra.benton@fda.hhs.gov; 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 "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product." Clinical pharmacology studies are part of a stepwise approach to develop the data and information needed to support a demonstration of biosimilarity. Adequate and well-conducted clinical pharmacology studies can address the residual uncertainty in biosimilarity assessment

from clinical perspectives and inform the design of subsequent studies to assess clinically meaningful differences between the biosimilar and the reference products. The draft guidance discusses some critical considerations related to clinical pharmacology testing for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. In its description of how to design and use clinical pharmacology studies to add to the totality of evidence that a proposed biological product is biosimilar to its reference product, the draft guidance is meant to assist sponsors in designing such studies in support of applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)). Scientific principles described in the draft guidance may also be informative for the development of certain biological products under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

This draft guidance is one in a series that FDA is developing to implement the BPCI Act and 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 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. The Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information submitted under section 351(k) applications for biosimilars is approved under OMB control number 0910-0719. The collection of information submitted under 21 CFR part 312 is approved under OMB control number 0910-0014.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance 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 draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: May 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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