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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations, which are not expected to change as a result of the guidance. 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 related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application (BLA) under section 351(a) of the PHS Act, which is covered under part 601 (21 CFR part 601) and approved under OMB control number 0910–0338; and (4) a BLA under section 351(k), which is covered under part 601 and approved under OMB control number 0910–0719.

IV. Electronic Access

Persons with access to the Internet may obtain the document 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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10063 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0605]

Scientific Considerations in Demonstrating Biosimilarity to a Reference Product; 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 guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting a marketing application through an abbreviated licensure pathway. This guidance gives an overview of FDA's approach to determining biosimilarity.

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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or 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 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: 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, 301–796–1042, or Stephen Ripley, 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 guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product is ''biosimilar'' [1] to a reference product for the purpose of submitting a marketing application through the abbreviated licensure pathway under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)).

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted as part of the Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the PHS Act for biological products demonstrated to be biosimilar to, or interchangeable with, a reference product. Under this abbreviated licensure pathway, FDA will license a proposed biological product submitted under section 351(k) of the PHS Act if FDA ''determines that the information submitted in the application . . . is sufficient to show that the biological product is biosimilar to the reference product. . . .'' and the 351(k) applicant (or other appropriate person) consents to an inspection of the facility that is the subject of the application (*i.e.,* a facility in which the proposed biological product is manufactured, processed, packed, or held).[2] The guidance gives an overview of FDA's approach to determining biosimilarity. FDA intends to consider the totality of the evidence submitted in a 351(k) application and is recommending that sponsors use a stepwise approach in their development of biosimilar products. The guidance discusses important scientific considerations in demonstrating biosimilarity, including:

- A stepwise approach to demonstrating biosimilarity, which can include a comparison of the proposed product and the reference product with

[1] In section 7002(b)(3) of the Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. 111–148, ''biosimilar'' or ''biosimilarity'' means ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components,'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.''

[2] Section 7002(a)(2) of the Affordable Care Act, adding section 351(k)(3) of the PHS Act (citing section 351(a)(2)(C) of the PHS Act).

respect to structure, function, animal toxicity, human pharmacokinetics (PK) and pharmacodynamics (PD), clinical immunogenicity, and clinical safety and effectiveness;

- The *totality-of-the-evidence* approach that FDA will use to review applications for biosimilar products, consistent with a longstanding Agency approach to evaluation of scientific evidence; and
- General scientific principles in conducting comparative structural analyses, functional assays, animal testing, human PK and PD studies, clinical immunogenicity assessment, and comparative clinical trials (including clinical study design issues).

In the **Federal Register** of February 15, 2012 (77 FR 8883), FDA announced the availability of the draft guidance of the same title dated February 2012. FDA received a number of comments on the draft guidance. In response to these comments, FDA provides further clarification of the scientific considerations applicable to the conduct of comparative structural analysis, functional assays, animal studies, and clinical testing. The final guidance also provides additional information on clinical trial design and selection of study endpoint and population. It also explains FDA's current thinking on when a comparative clinical trial may not be needed. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes and replaces the draft guidance dated February 2012.

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 scientific considerations in demonstrating biosimilarity to a reference product. 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. The Paperwork Reduction Act of 1995

This guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). This guidance references information collections that are already approved by OMB and are not expected to change as a result of the guidance. This includes information collections related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB Control No. 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application under section 351(a) of the PHS Act, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0338; and (4) a biologics license application under section 351(k) of the PHS Act, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0719.

IV. Electronic Access

Persons with access to the Internet may obtain the document 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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10062 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0611]

Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009; 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 guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' This guidance is intended to provide answers to common questions from sponsors interested in developing proposed biosimilar products, biologics license application (BLA) holders, and other interested parties regarding FDA's interpretation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). This guidance finalizes several questions and answers (Q&As) from the draft guidance entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'' issued February 15, 2012.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; 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 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: 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, 301–796–1042; or Stephen Ripley, 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 guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the