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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. The Paperwork Reduction Act

This draft guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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). In particular, the draft guidance refers to information collections related to the submission of 351(k) application. In accordance with the PRA, FDA is soliciting public comment, in a separate document published elsewhere in this issue of the **Federal Register** (see ''Agency Information Collection Activities: Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications'') on the information collection associated with the submission of a 351(k) application. FDA will also seek OMB approval for this information collection.

In addition, this draft guidance references other information collections that are already approved by OMB and are not expected to change as a result of the draft guidance.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 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, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0338; and (4) labeling, which is covered under 21 CFR 201.57 and approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory Information/default.htm,* or *http://www.regulations.gov*.

Dated: February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3552 Filed 2–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0602]

Draft Guidance for Industry on Quality Considerations in Demonstrating Biosimilarity to a Reference Protein 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 ''Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product.'' This draft guidance is intended to provide sponsors with an overview of analytical factors to consider when assessing biosimilarity between a proposed protein product and a reference product for the purpose of submitting a marketing application through an abbreviated licensure pathway. This draft guidance provides an overview of FDA's approach to quality considerations in determining biosimilarity.

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 comments 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 April 16, 2012.

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, 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: 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 (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 ''Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product.'' This draft guidance is intended to provide sponsors with an overview of analytical factors to consider when assessing biosimilarity between a proposed protein product and 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)). Although the 351(k) pathway applies generally to biological products, this draft guidance focuses on therapeutic protein products.

The Biologics Price Competition and Innovation Act of 2009, enacted as part of the Patient Protection and Affordable Care Act (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).[1]

All product applications should contain a complete and thorough Chemistry, Manufacturing, and Controls (CMC) section that provides the necessary and appropriate information (*e.g.,* characterization, adventitious agent safety, process controls, and specifications) for the product to be adequately reviewed.[2] This draft guidance describes important factors for consideration when assessing whether therapeutic protein products are highly similar, including:

- Expression System
- Manufacturing Process
- Assessment of Physiochemical Properties
- Functional Activities
- Receptor Binding and Immunochemical Properties
- Impurities
- Reference Product and Reference Standards
- Finished Drug Product
- Stability

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 quality considerations in demonstrating biosimilarity to a reference protein 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. The Paperwork Reduction Act

This draft 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). In particular, the draft guidance refers to information collections related to the submission of a 351(k) application. In accordance with the PRA, FDA is soliciting public comment, in a separate document published elsewhere in this issue of the **Federal Register** (see ''Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications'') on the information collection associated with the submission of a 351(k) application. FDA will also seek OMB approval for this information collection.

In addition, this draft guidance references other information collections that are already approved by OMB and are not expected to change as a result of the draft 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 number 0910–0014; (2) a new drug application which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; and (3) a biologics license application which is covered under 21 CFR part 601 and approved under OMB control number 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3550 Filed 2–14–12; 8:45 am]

BILLING CODE 4160–01–P

[1] 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).

[2] For CMC requirements for submission of a marketing application, applicants should consult current regulations, the *Guidance for Industry for the Submission on Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In-vivo Use* (issued jointly by CBER and CDER, August 1996), and other applicable FDA guidance documents.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0611]

Draft Guidance for Industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009; 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 ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' This draft 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).

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 April 16, 2012. Submit either electronic or written comments on the proposed collection of information by April 16, 2012.

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 the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the 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.