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adventitious agent safety, process controls, and specifications) for the product to be adequately reviewed.[2] This draft guidance describes important factors for consideration when assessing whether therapeutic protein products are highly similar, including: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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on quality considerations in demonstrating biosimilarity to a reference protein product.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This draft guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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 In particular, the draft guidance refers to information collections related to the submission of a 351(k) application.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In addition, this draft guidance references other information collections that are already approved by OMB and are not expected to change as a result of the draft guidance.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]

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[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.

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 ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' This draft guidance provides answers to common questions from sponsors interested in developing proposed biosimilar products, BLA holders, and other interested parties regarding FDA's interpretation of the BPCI Act.

The BPCI Act, enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. This draft guidance describes FDA's current interpretation of certain statutory requirements added by the BPCI Act and includes questions and answers (Q&As) in the following categories:

- Biosimilarity or Interchangeability
- Provisions Related to Requirement to Submit a BLA for a ''Biological Product''
- Exclusivity

The Q&A format is intended to promote transparency and facilitate development programs for proposed biosimilar products by addressing questions that may arise in the early stages of development. In addition, these Q&As respond to questions the Agency has received from prospective BLA and new drug application (NDA) applicants regarding the appropriate statutory authority under which certain products will be regulated.

FDA intends to update this guidance to include additional Q&As as appropriate and intends to post information by Q&A number on FDA's Web site regarding the publication date of draft guidance Q&As for comment, the comment period, and the publication date of final guidance Q&As.

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 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. 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 (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 NDA, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) an NDA, 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.

The draft guidance also discusses the retention of reserve samples of the biological products used in comparative clinical pharmacokinetic and/or pharmacodynamic studies intended to support a proposed 351(k) application. Such reserve samples are samples of products or other physical objects exempt under 5 CFR 1320.3(h)(2), and thus not considered ''information'' as that term is defined under the PRA.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Detroit District Office, in co-sponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRB, and research sponsors.

Date and Time: The public workshop will be held on May 9 and 10, 2012, from 8 a.m. to 5 p.m.