manufactured, processed, packed, or held). 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. This draft guidance describes important factors for consideration when assessing whether therapeutic protein products are highly similar, including: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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on quality considerations in demonstrating biosimilarity to a reference protein product.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This draft guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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 The draft guidance, when finalized, will represent the Agency’s current thinking on quality considerations in demonstrating biosimilarity to a reference protein product.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.

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


Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2011–D–0611]


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.
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.