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In the **Federal Register** of February 15, 2012 (77 FR 8883), FDA announced the availability of the draft guidance of the same title dated February 2012. FDA received a number of comments on the draft guidance.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 The guidance announced in this notice finalizes and replaces the draft guidance dated February 2012.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

Biologics Price Competition and Innovation Act of 2009.'' This 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 (PHS Act) (42 U.S.C. 262(k)) for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed reference product. This guidance describes FDA's current interpretation of certain statutory requirements added by the BPCI Act and includes 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.

In the **Federal Register** of February 15, 2012 (77 FR 8885), FDA published a notice announcing the availability of a draft guidance entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' Although interested parties can comment on any guidance at any time, to ensure that the Agency considered comments on the draft guidance before beginning work on the final version of the guidance, FDA requested that interested parties submit comments by April 16, 2012. FDA's consideration of these comments, among other things, is reflected in a revised draft guidance and this final guidance. This guidance describes the status of the draft guidance Q&As provided in Revision 1 of the draft guidance entitled ''Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' and the status of the final guidance Q&As that are included in this guidance. FDA intends to update these guidances to include additional Q&As as appropriate.

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 ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' 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 refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). The submission of an investigational new drug application is covered under 21 CFR part 312 and approved under OMB control number 0910–0014. The submission of an NDA is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001. The submission of a BLA under section 351(a) of the PHS Act is covered under part 601 (21 CFR part 601) and approved under OMB control number 0910–0338. The submission of a BLA under section 351(k) of the PHS Act is covered under part 601 and approved under OMB control number 0910–0719. In the **Federal Register** of April 1, 2013 (78 FR 19492), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' The notice contained an analysis of the information collection burden resulting from the draft guidance, and will be submitted to OMB for approval before issuance of the final guidance.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *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. 2015–10064 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–2015–N–1305]

Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or ''we'') is announcing the availability of a risk assessment entitled ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products.'' The risk assessment is a tool to assist with reevaluating which animal drug residues should be included in milk testing programs. We undertook this project in response to a request from the National Conference on Interstate Milk Shipments (NCIMS).

DATES: Submit either electronic or written comments on the risk assessment by July 29, 2015.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the risk assessment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION:

I. Background

The NCIMS is a voluntary coalition that includes representatives from