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In the **Federal Register** of February 15, 2012 (77 FR 8885), FDA published a notice announcing the availability of a draft guidance entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.''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interested parties can comment on any guidance at any time, to ensure that the Agency considered comments on the draft guidance before beginning work on the final version of the guidance, FDA requested that interested parties submit comments by April 16, 2012. FDA's consideration of these comments, among other things, is reflected in a revised draft guidance and this final guidance. This guidance describes the status of the draft guidance Q&As provided in Revision 1 of the draft guidance entitled ''Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' and the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

Federal and State governments, the dairy industry, academia, and consumer groups. FDA collaborates with the NCIMS under a memorandum of understanding between the two entities. The NCIMS requested that we conduct an assessment of animal drug residues in the milk supply to inform potential changes to milk testing program requirements. In response, we developed a multicriteria-based ranking model of selected animal drugs used in dairy cows. The risk assessment provides a science-based, analytical approach to collate and incorporate relevant available data and information (Ref. 1). It provides a decision-support tool to assist with reevaluating which animal drug residues should be included in milk testing programs. The risk assessment also may be used to identify and prioritize research needs. The risk assessment model approach has undergone an independent external peer review. FDA's response to the peer review is available electronically on the FDA Web site (Ref. 2).

The muticriteria-based ranking model is based on four overarching criteria that collectively contribute to a drug's score and rank within the group of drugs evaluated: (1) The likelihood that the drug will be administered to lactating dairy cows; (2) the likelihood that, following administration, drug residues would be present in milk (bulk tank or bulk milk pickup tanker); (3) the relative extent to which consumers could be exposed to the drug residue via consumption of milk and milk products; and (4) the potential for a human health hazard given exposure to the drug residue. The risk assessment describes the ranking model structure, the scientific data and assumptions used to inform scoring in the model, and the ranking results. The risk assessment also identifies data gaps and research needs.

FDA invites comments that can help improve:

- The ranking model approach, including the specific criteria, scoring, and weighting scheme;
- the scientific data and assumptions used to inform scoring used in the model;
- the selection of animal drugs evaluated; and
- the clarity and the transparency of the risk assessment.

II. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**) regarding the risk assessment. 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. Electronic Access

Persons with access to the Internet may obtain the risk assessment at either *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm* or *http://www.regulations.gov.*

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products.'' Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm.*

2. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products: Peer Review Report.'' Accessible at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm.*

Dated: April 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10000 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–0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 8, 2015, from 9 a.m. to 5 p.m. and June 9, 2015, from 9 a.m. to 12 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503) Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3367, 240–402–5274, FAX: 301–847–3540, *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to join us in person, we encourage you to watch the free Webcast. Visit the Risk Communication Advisory Committee Web site at *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm.* The link will become active shortly before the open session begins at 9 a.m.

Agenda: On June 8 and 9, 2015, the Committee will discuss approaches to communicating information about fetal effects in product labeling for methadone or buprenorphine maintenance therapy for opioid addiction, and about the maternal benefits and risks of treatment, to best enable patients and health care providers to make informed decisions about the use of these drugs during pregnancy.

FDA intends to make background material available to the public no later