DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0234]

Clinical Pharmacology Data To Support a Demonstration of Biosimilarity to a Reference Product; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' This guidance is to assist the pharmaceutical industry and other investigators engaged in biosimilar product development in determining the clinical pharmacology data necessary for evaluation of a proposed biosimilar product. This guidance finalizes the draft guidance with the same name issued in May 2014. This guidance is one in a series of guidances that FDA is developing to implement the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–0234 for ''Clinical Pharmacology Data To Support a Demonstration of Biosimilarity to a Reference Product; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. 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.

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, 301–796–2500; 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 ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' This guidance is intended to assist the pharmaceutical industry and other investigators engaged in biosimilar product development with the design and use of clinical pharmacology data necessary for evaluation of a proposed biosimilar product. This guidance provides recommendations on how clinical pharmacology studies that assess the presence or absence of clinically meaningful differences between the proposed biosimilar product and the U.S.-licensed reference product should be conducted and analyzed to address questions arising during biosimilar product development.

Clinical pharmacology studies are part of a stepwise approach for developing the data and information needed to support a demonstration of biosimilarity. These studies can reduce the residual uncertainty in assessing the biosimilarity between a proposed biosimilar product and reference product and inform the design of subsequent clinical trials to assess clinically meaningful differences. This guidance is intended to assist sponsors in designing such studies in support of applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by the BPCI Act.[1] In particular, this guidance discusses certain critical considerations for using clinical pharmacology testing to support biosimilarity, approaches for developing the appropriate clinical pharmacology database to support a demonstration of biosimilarity, and the utility of modeling and simulation for designing and analyzing clinical trials. Scientific principles described in the guidance may also be informative for the development of certain biological products under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

On May 14, 2014, FDA issued a notice announcing the availability of a draft guidance with the same name as the current guidance to solicit comments from the public (79 FR 27622). After carefully reviewing received comments and in light of increased regulatory experience and the evolution of the science in biosimilar product development and evaluation, FDA has finalized that guidance with certain changes. These changes are for clarity, however, and are not substantive.

This guidance is one in a series that FDA is developing to implement the BPCI Act and is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on conducting clinical pharmacology studies in support of proposed biosimilar products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under section 351(k) applications for biosimilars is approved under OMB control number 0910–0719. The collection of information submitted under 21 CFR part 312 is approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the guidance 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: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31511 Filed 12–28–16; 8:45 am]

BILLING CODE 4164–01–P

[1] The BPCI Act was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4318]

Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities.'' This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by State-licensed nuclear pharmacies and Federal facilities that are not registered as outsourcing facilities. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it does not intend to take action for violations of certain provisions of the FD&C Act when a State-licensed nuclear pharmacy or Federal facility compounds or repackages radiopharmaceuticals.

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 February 27, 2017. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 27, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

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- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–4318 for ''Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities.'' Received