



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0611]

Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act.” The question and answer (Q&A) format is intended to inform prospective applicants and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars, as well as to describe FDA’s interpretation of certain statutory requirements added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). This draft guidance document provides new Q&As. It does not replace the draft guidance document entitled “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),” issued December 12, 2018.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2011-D-0611 for "Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at

the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993, 301-796-1042, sandra.benton@fda.hhs.gov, 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, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act.” The Q&A format is intended to inform prospective applicants and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars, as well as to describe FDA’s interpretation of certain statutory requirements added by the BPCI Act.

The BPCI Act created an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111-148)). FDA believes that guidance for industry that provides answers to commonly asked questions regarding FDA’s interpretation of the BPCI

Act will enhance transparency and facilitate the development and approval of biosimilar and interchangeable products.

FDA has been using the format of Q&A guidance to describe the Agency's thinking on and update certain information and recommendations relevant to the development of biosimilar and interchangeable products. This draft guidance document contains only Q&As that are in draft form. After FDA has considered any comments on the Q&As contained in this draft guidance received during the relevant comment period and, as appropriate, incorporated suggested changes to the Q&A, individual Q&As will be finalized and moved to the final guidance document "Questions and Answers on Biosimilar Development and the BPCI Act," which is updated as appropriate. The final guidance contains Q&As that have been through the public comment process and reflects FDA's current thinking on the topics described. A Q&A may be withdrawn and removed from the Q&A guidance documents if, for instance, the issue addressed in the Q&A has been addressed in another FDA guidance document. No such changes to currently issued draft or final guidance documents are being made in connection with the issuance of this draft guidance.

FDA has maintained the original numbering of the Q&As used in the December 2018 final guidance "Questions and Answers on Biosimilar Development and the BPCI Act" and the December 2018 draft guidance "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)." This draft guidance document provides new Q&As. It does not replace the draft guidance document entitled "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)," issued December 12, 2018.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The Q&As in this draft guidance, when finalized, will appear in the final guidance, and the final guidance will represent the current thinking of FDA on the Q&As posed in the "Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act." 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910-0014. The collections of information in 21 CFR 314.50 for submission of a new drug application have been approved under OMB control number 0910-0001. The collections of information in section 351(a) of the PHS Act and 21 CFR part 601 for submission of a biologics license application (BLA) have been approved under OMB control number 0910-0338. The collections of information in section 351(k) of the PHS Act and 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910-0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: November 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.