4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

New and Revised Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a revised draft guidance for industry entitled "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)." The question and answer (Q&A) format is intended to inform prospective applicants and facilitate the development of proposed biosimilar products and proposed interchangeable biosimilar products, as well as describe FDA's proposed interpretation of certain statutory requirements related to the abbreviated licensure pathway for biological products added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). This draft guidance revises and replaces the draft guidance for industry entitled "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)" issued September 17, 2021 to provide certain revisions to Q&As I.8, I.10, and I.19, which have been withdrawn from the final guidance entitled "Questions and Answers on Biosimilar Development and the BPCI Act" issued September 20, 2021.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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 "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)." 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 the 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. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010 or emailing industry.biologics@fda.hhs.gov. 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: Mustafa Unlu, Center for Drug Evaluation and Research (HF-22), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993-0001, 301-796-3396, CDER-BiologicsBiosimilarsInquiries@fda.hhs.gov; or Philip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)." The BPCI Act amended the Public Health Service Act (PHS Act) and other statutes to create 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's view is 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.

This draft guidance is a companion to the final guidance for industry issued in September 2021 entitled "Questions and Answers on Biosimilar Development and the BPCI Act." In this pair of guidance documents, FDA issues each Q&A in draft form in a draft guidance, receives comments on the draft Q&A and, as appropriate, moves the Q&A to the final guidance after reviewing comments and incorporating suggested changes to the Q&A. A Q&A that was

previously in the final guidance may be withdrawn and moved to a draft guidance if FDA determines that the Q&A should be revised in some respect and reissued in a revised draft Q&A for comment. Furthermore, a Q&A also may be withdrawn and removed from a Q&A guidance if, for instance, the concept(s) addressed by the Q&A is addressed, or would be addressed more appropriately, in a different FDA guidance document.

This draft guidance contains Q&As distributed for comment purposes only and includes proposed revisions to Q&As that appeared in previous versions of the final guidance documents. The final guidance contains Q&As that have been through the public comment process and reflects FDA's current thinking on the topics described. While these guidances have been revised over time, FDA has maintained the original numbering of the Q&As as they were published in the original versions of these guidances and subsequent revisions (available at https://www.regulations.gov/docket/FDA-2011-D-0611/document).

This draft guidance contains revised versions of three Q&As (Q&A I.8, Q&A I.10, and Q&A I.19). The revised Q&A I.8 is now organized into two parts: Part "a" describes FDA's updated recommendations regarding how a clinical study (such as an assessment of pharmacokinetics (PK)) comparing the proposed biosimilar with a non-U.S.-licensed comparator product could address, in part, the requirements under section 351(k)(2)(A) of the PHS Act and support a demonstration of biosimilarity to the U.S.-licensed reference product in certain circumstances. Part "a" also identifies circumstances under which clinical data derived from a study using a non-U.S.-licensed comparator product may be acceptable. Part "b" elaborates on recommendations regarding the nature and extent of comparative analytical data between the non-U.S.-licensed comparator product and the U.S.-licensed reference product for purposes of the comparative analytical assessment. FDA is specifically requesting public comment on the utility of an analytical comparison between the proposed biosimilar product and the non-U.S.-licensed comparator product as part of the scientific justification to support the relevance of

clinical data with a non-U.S.-licensed comparator product to a demonstration of biosimilarity to the U.S.-licensed reference product.

Additionally, minor updates were made to Q&As I.10 and Q&A I.19 for clarity and to align with revised Q&A I.8. FDA's intent is that Part "a" of Q&A I.8 may inform a future revised guidance for industry entitled "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product" and Part "b" may inform future revisions to a guidance for industry entitled "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations" as appropriate.

At this time, FDA is also withdrawing Q&As I.8, I.10, and I.19 from the final guidance entitled "Questions and Answers on Biosimilar Development and the BPCI Act" issued September 20, 2021, and reissuing the final guidance (with certain updates to the introductory text) solely for the purpose of withdrawing these particular Q&As. The Agency continues to evaluate other Q&As in this final guidance as part of its efforts to further enhance efficiency in biosimilar development programs and intends to update any Q&As that may no longer reflect the Agency's current thinking, as appropriate.

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 current thinking of FDA on "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)." 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information

are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 relating to submission of an investigational new drug application have been approved under OMB control number 0910-0014. The collections of information relating to the submission of a BLA under section 351(k) of the PHS Act, including the submission of data from comparative analytical assessments and a clinical study or studies (including the assessment of immunogenicity and PK or pharmacodynamics), that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed, as well as formal meetings between FDA and sponsors, have been approved under OMB control number 0910-0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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.

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