New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact (CDER) Sandra Benton at 301-796-1042 or (CBER) Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2018
Biosimilars

Revision 2

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New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

INTRODUCTION

This draft guidance document provides answers to common questions from prospective applicants and other interested parties regarding the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The question and answer (Q&A) format is intended to inform prospective applicants and facilitate the development of proposed *biosimilars* and *interchangeable biosimilars*,[2] as well as to describe FDA's interpretation of certain statutory requirements added by the BPCI Act.

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 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) (ACA)). 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. In addition, these Q&As respond to questions the Agency has received from prospective applicants regarding

[1] This draft guidance has been prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency).

We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[2] In this draft guidance, the following terms are used to describe biological products licensed under section 351(k) of the PHS Act: (1) *biosimilar* or *biosimilar product* refers to a product that FDA has determined to be biosimilar to the reference product (see sections 351(i)(2) and 351(k)(2) of the PHS Act) and (2) *interchangeable biosimilar* or *interchangeable product* refers to a biosimilar product that FDA has also determined to be interchangeable with the reference product (see sections 351(i)(3) and 351(k)(4) of the PHS Act). Biosimilarity, interchangeability, and related issues are discussed in more detail in the Background section of this draft guidance.

the appropriate statutory authority under which certain products will be regulated. FDA intends to update this draft guidance document to include additional Q&As as appropriate.

This draft guidance document revises the draft guidance document, *Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.*[3] The draft guidance document contains Q&As distributed for comment purposes only and includes new Q&As, as well as revisions to Q&As that appeared in previous versions of the draft or final guidance documents. Additional information about the Q&A format for this draft guidance document is provided in the Background section.

FDA is also issuing a final guidance document entitled *Questions and Answers on Biosimilar Development and the BPCI Act.* This final guidance document is part of a series of guidance documents that FDA has developed to facilitate development of biosimilar and interchangeable products. The final guidance documents issued to date address a broad range of issues, including:

- Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product (April 2015)
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (April 2015)
- Questions and Answers on Biosimilar Development and the BPCI Act (December 2018)
- Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (December 2016)
- Labeling for Biosimilar Products (July 2018)

In addition, FDA has published draft guidance documents related to the BPCI Act, which, when finalized, will represent FDA's current thinking. These draft guidance documents include:

- Considerations in Demonstrating Interchangeability With a Reference Product (January 2017)
- Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products (June 2018)
- Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (August 2014)

[3] FDA has adjusted the title of this draft guidance to more clearly communicate that this draft guidance contains *draft* questions and answers.

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