TABLE 1—STATUS OF DRAFT GUIDANCE Q&AS AND FINAL GUIDANCE Q&AS—Continued

Q&A category	Q&A Nos.	Previous guidance location	Current guidance location
Part II. Provisions Related to Requirements to Submit a Biologics License Application (BLA) for a ''Biological Product''.	Q.II.1	Final	Draft.
	Q.II.2	Final	Final.
	Q.II.3	Draft	Final.
Part III. Exclusivity	Q.III.1	Draft	Final.
	Q.III.2	Final	Final.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The Q&As in this draft guidance, when finalized, will appear in the final guidance, and the final guidance will represent the current thinking of FDA on the Q&As posed in the ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).'' 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. This guidance is not subject to Executive Order 12866.

FDA is announcing, in a separate document published elsewhere in this issue of the **Federal Register**, the availability of the guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act.''

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This draft guidance refers to previously approved collections of information found in FDA regulations.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. 3501–3520). 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 part 601 (21 CFR part 601) for submission of a BLA have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and part 601 for submission of a BLA have been approved under OMB control number 0910–0719. The collections of information for submission of a meeting package to the appropriate review division with the meeting request as described in the draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products'' have been approved under OMB control number 0910–0802.

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* or *https://www.regulations.gov.*

Dated: December 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26852 Filed 12–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0611]

Biosimilars: Questions and Answers on Biosimilar Development and the Biologics Price Competition and Innovation Act of 2009; 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 final guidance for industry entitled ''Questions and Answers 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 guidance document revises the final guidance document entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'' issued April 28, 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on December 12, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 ''Questions and Answers on Biosimilar Development and the BPCI Act; Guidance for Industry.'' 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.

• 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.gpo.gov/fdsys/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.

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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6522, Silver Spring, MD 20993, 301–796–1042, 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 final guidance for industry entitled ''Questions and Answers 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 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)). 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 intends to update this guidance document to include additional Q&As as appropriate.

This final guidance document is a companion to the draft guidance document entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).'' In this pair of guidance documents, FDA issues each Q&A in draft form in the draft guidance document, receives comments on the draft Q&A, and, as appropriate, moves the Q&A to this final guidance document, after reviewing comments and incorporating suggested changes to the Q&A, when appropriate. This final guidance document contains Q&As that have been through the public comment process and reflects FDA's current thinking on the topics described. This guidance document revises the final guidance document entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'' to clarify and update certain Q&As and to add new Q&As. For certain Q&As, FDA has updated the Q&A by referring the reader to a separate guidance document that provides additional information on the topic. In addition, 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 a separate FDA guidance document. For example, Q&A I.11 has been withdrawn as the issues addressed in that question are addressed in the guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.''

FDA has maintained the original numbering of the Q&As used in the April 2015 final guidance document (''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'') and May 2015 draft guidance document (''Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'').

TABLE 1—STATUS OF DRAFT GUIDANCE Q&AS AND FINAL GUIDANCE Q&AS

Q&A category	Q&A Nos.	Previous guidance location	Current guidance location
Part I. Biosimilarity or Interchangeability	Q.I.1	Final	Final

TABLE 1—STATUS OF DRAFT GUIDANCE Q&AS AND FINAL GUIDANCE Q&AS—Continued

Q&A category	Q&A Nos.	Previous guidance location	Current guidance location
	Q.I.2	Final	Final.
	Q.I.3	Final	Final.
	Q.I.4	Final	Final.
	Q.I.5	Final	Final.
	Q.I.6	Final	Final.
	Q.I.7	Final	Final.
	Q.I.8	Final	Final.
	Q.I.9	Draft	Final.
	Q.I.10	Draft	Final.
	Q.I.11	Final	Withdrawn.
	Q.I.12	Final	Draft.
	Q.I.13	Draft	Final.
	Q.I.14	Draft	Final.
	Q.I.15	Final	Final.
	Q.I.16	Draft	Draft.
	Q.I.17	Draft	Final.
	Q.I.18	Draft	Final.
	Q.I.19	Draft	Final.
	Q.I.20		Draft.
	Q.I.21		Draft.
	Q.I.22		Draft.
	Q.I.23		Draft.
	Q.I.24		Draft.
Part II. Provisions Related to Requirements to Submit a Biologics License Application (BLA) for a ''Biological Product''.	Q.II.1	Final	Draft.
	Q.II.2	Final	Final.
	Q.II.3	Draft	Final.
Part III. Exclusivity	Q.III.1	Draft	Final.
	Q.III.2	Final	Final.

This guidance finalizes certain Q&As that were included in the draft guidance issued on May 13, 2015. FDA considered written comments the Agency received regarding these Q&As, and made changes to the Q&As, as appropriate. Editorial changes were made primarily for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Questions and Answers 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. This guidance is not subject to Executive Order 12866.

FDA is announcing, in a separate document published elsewhere in this issue of the **Federal Register**, the availability of the draft guidance for industry entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).''

II. Paperwork Reduction Act of 1995

This 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. 3501–3520). 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 under part 601 (21 CFR part 601) for submission of a BLA have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act under part 601 for submission of a BLA have been approved under OMB control number 0910–0719. The collections of information for submission of a meeting package to the appropriate review division with the meeting request as described in the draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products'' have been approved under OMB control number 0910–0802.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: December 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26853 Filed 12–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7007–N–06]

60-Day Notice of Proposed Information Collection: Data Collection for EnVision Center Demonstration Sites

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information.