and regulations. This guidance is not subject to Executive Order 12866.

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This draft guidance refers to previously approved collections of information found in FDA regulations.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 collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001; the collection of information in 21 CFR parts 601 and 610 has been approved under OMB control number 0910–0338; the collection of information in 21 CFR 600.80 through 600.90 has been approved under OMB control number 0910–0308; and the collection of information in 21 CFR 201.56, 201.57, and 201.80 has been approved under OMB control number 0910–0572. In addition, the collections of information for applications submitted under section 351(k) of the PHS Act (42 U.S.C. 262(k)) 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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26855 Filed 12–11–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4750]

Interpretation of the ''Deemed To Be a License'' Provision of 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 ''Interpretation of the 'Deemed To Be a License' Provision of the Biologics Price Competition and Innovation Act of 2009.'' This guidance describes FDA's interpretation of the statutory provision under which an application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, will be deemed to be a license for the biological product under the Public Health Service Act (PHS Act) on March 23, 2020. Specifically, this guidance describes FDA's interpretation of the ''deemed to be a license'' provision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) for biological products that are approved under the FD&C Act as of March 23, 2020. This guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under the FD&C Act on or before March 23, 2020, to facilitate alignment of product development plans with FDA's interpretation of the transition provision of the BPCI Act.

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–2015–D–4750 for ''Interpretation of the 'Deemed To Be a License' Provision of the Biologics Price Competition and Innovation Act of 2009; Guidance for Industry; Availability.'' 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 to 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: Janice Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6270, Silver Spring, MD 20993–0002, 301–796–3475; 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 ''Interpretation of the 'Deemed To Be a License' Provision of the Biologics Price Competition and Innovation Act of 2009.''

This guidance describes FDA's interpretation of the provision of the BPCI Act under which an application for a biological product approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) as of March 23, 2020, will be deemed to be a license for the biological product under section 351 of the PHS Act (42 U.S.C. 262) on March 23, 2020. Specifically, this guidance describes FDA's interpretation of the ''deemed to be a license'' provision in section 7002(e) of the BPCI Act for biological products that are approved under section 505 of the FD&C Act as of March 23, 2020 (the transition date). This guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under section 505 of the FD&C Act on or before March 23, 2020, to facilitate alignment of product development plans with FDA's interpretation of section 7002(e) of the BPCI Act.

Although the majority of therapeutic biological products have been licensed under section 351 of the PHS Act, some protein products historically have been approved under section 505 of the FD&C Act. On March 23, 2010, the BPCI Act was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148). The BPCI Act clarified the statutory authority under which certain protein products will be regulated by amending the definition of a ''biological product'' in section 351(i) of the PHS Act to include a ''protein (except any chemically synthesized polypeptide),'' and describing procedures for submission of a marketing application for a ''biological product.'' FDA previously stated its interpretation of the statutory terms ''protein'' and ''chemically synthesized polypeptide'' in the amended definition of ''biological product'' (see FDA's draft guidance for industry entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),'' available on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Elsewhere in this issue of the **Federal Register**, FDA also has issued a proposed rule to amend its regulation that defines ''biological product'' to incorporate changes made by the BPCI Act, and to provide its interpretation of the statutory terms ''protein'' and ''chemically synthesized polypeptide.'' When final, this regulation will codify FDA's interpretation of these terms.

The BPCI Act requires that a marketing application for a ''biological product'' (that previously could have been submitted under section 505 of the FD&C Act) must be submitted under section 351 of the PHS Act; this requirement is subject to certain exceptions during a 10-year transition period ending on March 23, 2020 (see section 7002(e)(1)–(3) and (e)(5) of the BPCI Act). On March 23, 2020, an approved application for a biological product under section 505 of the FD&C Act shall be deemed to be a license for the biological product under section 351 of the PHS Act (see section 7002(e)(4) of the BPCI Act). Among other things, while section 7002(e)(4) of the BPCI Act explicitly provides that an approved application under section 505 of the FD&C Act shall be deemed to be a license on March 23, 2020, the statute does not provide a means for deeming an approved new drug application (NDA) to be an approved biologics license application (BLA) prior to, or after, the transition date. Therefore, FDA interprets section 7002(e) of the BPCI Act to plainly mean that, on March 23, 2020, only approved NDAs will be deemed to be BLAs. After March 23, 2020, the Agency will not approve any application submitted under section 505 of the FD&C Act for a biological product subject to the transition provision that is pending or tentatively approved. Such an application may, for example, be withdrawn and submitted under section 351(a) or 351(k) of the PHS Act, as appropriate. In the final guidance, FDA provides recommendations to minimize the impact on development programs for any proposed biological products intended for submission under section 505 of the FD&C Act that may not be able to receive final approval by March 23, 2020.

In the **Federal Register** of March 14, 2016 (81 FR 13373), FDA announced the availability of the draft of this guidance. FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. This final guidance explains that FDA interprets section 7002(e) of the BPCI Act and section 351 of the PHS Act to mean that an approved NDA for a biological product that will be deemed to be ''licensed'' under section 351(a) of the PHS Act on March 23, 2020, can be a reference product for a proposed biosimilar product or a proposed interchangeable product (see section 351(i)(4) of the PHS Act). However, a biological product that was first approved in an NDA under section 505 of the FD&C Act and deemed ''licensed'' under section 351(a) of the PHS Act on March 23, 2020, will not have been ''first licensed under subsection (a)'' for purposes of section 351(k)(7) of the PHS Act. Thus, such a biological product will not be eligible for exclusivity under section 351(k)(7)(A) and (B) of the PHS Act. Moreover, FDA interprets the limitations on eligibility for reference product exclusivity in section 351(k)(7)(C) of the PHS Act to apply to any reference product. The guidance also clarifies the Agency's approach to supplements submitted to an approved NDA for a biological product before March 23, 2020, that are pending on the transition date.

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 ''Interpretation of the 'Deemed To Be a License' Provision of the Biologics Price Competition and Innovation Act of 2009.'' 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.

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 collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014; the collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001; the collection of information in 21 CFR part 601 has been approved under OMB control number 0910–0338; and the collection of information for applications submitted under section 351(k) of the PHS Act has been approved under OMB control number 0910–0719; the collection of information in FDA's guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants'' has been approved under OMB control number 0910–0802; and the collection of information in FDA's guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' has been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *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. 2018–26854 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]

New and Revised Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation Act (Revision 2); 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 ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).'' 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 revises the draft guidance document entitled ''Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' issued May 13, 2015, to provide new and revised Q&As.

DATES: Submit either electronic or written comments on the draft guidance by February 11, 2019 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 2); Draft 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