



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4750]

Implementation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Implementation of the ‘Deemed to be a License’ Provision of the Biologics Price Competition and Innovation Act of 2009.” This draft guidance describes FDA’s approach to implementation of the statutory provision under which an application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) on or before 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 Specifically, this draft guidance describes FDA’s interpretation of the “deemed to be a license” provision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) for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 have been or will be approved under the FD&C Act on or before March 23, 2020. This draft guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under the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 the transition provisions of the BPCI Act.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 “Implementation of the ‘Deemed to be a License’ Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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; 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 draft 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. 6268, Silver Spring, MD 20993-0002, 301-796-3601; 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 draft guidance for industry entitled “Implementation of the ‘Deemed to be a License’ Provision of the Biologics Price Competition and Innovation Act of 2009.” This draft guidance describes FDA’s approach to implementation of the provision of the BPCI Act under which an application for a biological product approved under section 505 of the FD&C Act (21 U.S.C. 355) on or before 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 draft 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 have been or will be approved under section 505 of the FD&C Act on or before March 23, 2020. This draft 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 changed 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).” FDA has interpreted the statutory terms “protein” and “chemically synthesized polypeptide” to implement the amended definition of “biological product” (see FDA’s guidance for industry entitled “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,” available on FDA’s Web site at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>).

The BPCI Act requires that a marketing application for a “biological product” 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, because the BPCI Act provides only that an application that is approved on March 23, 2020, shall be deemed to be a license, FDA interprets section 7002(e) of the BPCI Act to mean that the Agency will not approve any application under section 505 of the FD&C Act for a biological product subject to the transition provisions that is pending or tentatively approved “on” March 23, 2020, even though section 7002(e)(2) of the BPCI Act expressly permits submission of an application under section 505 of the FD&C Act “not later than” March 23, 2020, if certain criteria are met. Such an application may, for example, be withdrawn and resubmitted under section 351(a) or 351(k) of the PHS Act, as appropriate. FDA recognizes that this interpretation could have a significant impact on development programs for any proposed protein products intended for submission under section 505 of the FD&C Act that are not able to receive final approval by March 23, 2020, and provides recommendations to sponsors in the draft guidance.

We invite comment on the Agency's approach to implementation of the "deemed to be a license" provision of the BPCI Act, as described in the draft guidance.

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 implementation of the "deemed to be a license" provision of 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 that 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 0910-0014; the collection of information in 21 CFR part 314 has been approved under 0910-0001; the collection of information in 21 CFR part 601 has been approved under 0910-0338; and the collection of information for applications submitted under section 351(k) of the PHS Act has been approved under 0910-0719. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the Internet may obtain the document at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>.

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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