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This draft guidance refers to previously approved collections of information found in FDA regulations.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Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Announcements. The guidance is published in the Federal Register on December 12, 2018.

ADDRESS: 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 docket, 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
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“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. Send
one self-addressed adhesive label to
assist the Office in processing your
requests.

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,
355) as of March 23, 2020, will be
deemed to be a license for the biological
product under section 351 of the PHS
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/
GuidanceComplianceRegulatory
Information/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 the 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

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
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 316 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


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 BPCIA 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 (BPCIA 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 BPCIA 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