Based upon the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of any of the receiverships, such comment must be made in writing, identify the receivership to which the comment pertains, and be sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of the above-mentioned receiverships will be considered which are not sent within this time frame.

(Authority: 12 U.S.C. 1819)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 14, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–20223 Filed 9–17–21; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0611]

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, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised 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, and also describes 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 ''Questions and Answers on Biosimilar Development and the BPCI Act'' issued December 12, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2021.

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.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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. 22, Rm. 1132, Silver Spring, MD 20993, 301–796–1042, *Sandra.Benton@fda.hhs.gov* 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, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised 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, and also describe FDA's interpretation of certain statutory requirements added by the BPCI Act.

The BPCI Act created an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) 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 to include additional Q&As as appropriate.

FDA issues biosimilar Q&A guidances that contain Q&As about biosimilar and interchangeable products. This final guidance document contains all Q&As that are in final form. The November 2020 draft guidance entitled ''Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act'' (Additional Draft Q&A Guidance) and the draft guidance entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)'' (New and Revised Draft Q&A Guidance) contain draft Q&As. After FDA has considered any comments on the Q&As contained in the draft guidances, received during the relevant comment period and, as appropriate, incorporated suggested changes to the Q&A, individual Q&As will be moved to the final guidance document. 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 ''Questions and Answers on Biosimilar Development and the BPCI Act'' to clarify and update certain Q&As and add additional Q&As. For certain Q&As, FDA 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.

FDA has maintained the original numbering of the Q&As used in the December 2018 final guidance, ''Questions and Answers on Biosimilar Development and the BPCI Act,'' the December 2018 draft guidance, ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),'' and the Additional Draft Q&A Guidance.

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

Q&A category	Q&A No.	Previous guidance location	Current guidance location
Part I. Biosimilarity or Interchangeability.	Q.I.1	Final	Final.
	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	Final	Final.
	Q.I.10	Final	Final.
	Q.I.11	Withdrawn	Withdrawn.
	Q.I.12	Draft	Draft.*
	Q.I.13	Final	Final.
	Q.I.14	Final	Final.
	Q.I.15	Final	Final.
	Q.I.16	Draft	Final.
	Q.I.17	Final	Final.
	Q.I.18	Final	Final.
	Q.I.19	Final	Final.
	Q.I.20	Draft	Final.
	Q.I.21	Draft	Final.
	Q.I.22	Draft	Final.
	Q.I.23	Draft	Withdrawn.
	Q.I.24	Draft	Final.
	Q.I.25		Draft.
	Q.I.26		Draft.
	Q.I.27		Draft.
	Q.I.28		Draft.
Part II. Provisions Related to Requirements to Submit a Biologics License Application (BLA) for a ''Biological Product''.	Q.II.1	Draft	Withdrawn.
	Q.II.2	Final	Final.

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

Q&A category	Q&A No.	Previous guidance location	Current guidance location
Part III. Exclusivity	Q.II.3	Final	Final.
	Q.III.1	Final	Final.
	Q.III.2	Final	Final.

*The draft Q&A continues to be available in the New and Revised Draft Q&A Guidance (Revision 3). All other draft Q&As are available in the Additional Draft Q&A Guidance.

This guidance finalizes all but three of the Q&As that were included in the draft guidance ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)'' issued on December 12, 2018. FDA considered comments it received regarding these Q&As, and made changes to the Q&As, as appropriate; for example, providing additional and clearer information in Q.I.16 and providing additional information about text in the labeling for a biosimilar in Q.I.22. FDA also made certain clarifying and editorial changes to update previously finalized Q&As. Editorial changes were made primarily for clarification.

FDA has retained Q.I.12 in draft and transferred it to ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3).'' This draft Q&A addresses how an applicant can demonstrate that its proposed injectable biosimilar product or proposed injectable interchangeable product has the same ''strength'' as the reference product. FDA withdrew Q.I.23, which addressed a process for obtaining certain letters related to reference product access for testing for products with risk evaluation and mitigation strategy with elements to assure safe use. In light of the enactment of the Further Consolidated Appropriations Act, 2020 (FCA Act) (Pub. L. 116–94), which includes provisions related to this topic (see Division N, section 610, of the FCA Act (21 U.S.C. 355–2)), FDA intends to issue guidance describing how the existing process for obtaining these letters is being aligned with the framework set forth in the new law. FDA also withdrew Q.II.1, which addressed the definition of ''protein.'' For information on the definition of ''protein'' in section 351(i)(1) of the PHS Act, see the final rule entitled ''Definition of the Term 'Biological Product' '' (85 FR 10057, February 21, 2020; 21 CFR 600.3(h)(6)).

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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 part 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 21 CFR part 601 for submission of a biologics license application (BLA) have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the final guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: September 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20255 Filed 9–17–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's National Advisory Council on Migrant Health (NACMH or Council) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh.*

DATES: November 2–5, 2021; 12:30 p.m.–4:30 p.m. Eastern Time each day.

ADDRESSES: This meeting will be held by webinar. Instructions for joining the meeting will be posted on the NACMH website 30 business days before the meeting date. For meeting information updates, go to the NACMH website at: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh.*

FOR FURTHER INFORMATION CONTACT: Esther Paul, NACMH Designated Federal Officer, Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–594–4300; or *epaul@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACMH is a non-discretionary advisory body mandated by the Public Health Service Act, Title 42 U.S.C. 218, to advise, consult with, and make recommendations to the Secretary of the Department of Health and Human Services and the Administrator of HRSA regarding the organization, operation, selection, and funding of migrant health centers and other entities funded under section 330(g) of the Public Health