4. What is the generally achievable percent coverage [2] of the HCP spectrum for your HCP quantification assay? What considerations, (*e.g.,* percent coverage of HCPs, other coverage characteristics, etc.), are important in choosing methods to evaluate HCPs?

5. Are there any qualitative or quantitative characteristics of HCPs associated with a higher likelihood of adverse clinical sequelae?

6. What tools (in silico, in vitro or in vivo studies) do you currently use or plan to use to compare the potential immunogenicity risk of two products with different HCP profiles? What is your approach to risk assessment of HCPs based upon such data?

The public comments collected will help FDA develop recommendations on how HCP control and characterization can support comparative immunogenicity risk assessment between a recombinant follow-on peptide and the listed product.

III. Electronic Access

Persons with access to the internet may obtain relevant guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-peptide-drug-products.*

Dated: July 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16356 Filed 7–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3228]

Biosimilar Product Development Guidance; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to obtain information and comments that will assist the Agency in assessing how best to advance the development of new biosimilar biological products (biosimilars or biosimilar products), as part of the Biosimilar User Fee Amendments of 2022 (BsUFA III). As FDA continues to advance the development of biosimilars, we are seeking input from industry on whether biosimilar product development would be best served by focusing on product class-specific guidance documents that address common development issues that apply to a broad class of products, or by developing product-specific guidance documents, similar to the approach taken in the Generic Drug User Fee Amendments (GDUFA) program.

DATES: Submit either electronic or written comments, data, or information by October 23, 2024.

ADDRESSES: You may submit data, information, and comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 23, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–3228 ''Biosimilar Product Development Guidance; Establishment of a Public Docket; Request for Information and Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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

[2] HCP coverage is an estimate of the percentage of HCPs specific to a cell substrate detected or covered by the capture antibodies of the ELISA. This coverage analysis is often done using 2D techniques.

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.

FOR FURTHER INFORMATION CONTACT: Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993–0002, 301–796–2882, *Tiana.Barnes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Biosimilar User Fee Act reauthorization, known as BsUFA III,[1] authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar product development and review of applications submitted under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)). An application submitted under section 351(k) of the PHS Act must demonstrate, among other things, that a proposed biosimilar product is highly similar to, and has no clinically meaningful differences from, an FDA-licensed reference product. To date, FDA has issued a series of guidance documents to facilitate development of biosimilar products. Under section 351(k)(8)(D) of the PHS Act, if FDA issues product class-specific guidance with respect to the licensure of biosimilar products, the guidance must include a description of the criteria that FDA will use to determine whether a biological product is highly similar to a reference product in such product class and the criteria, if available, that FDA will use to determine whether a biological product meets the standards for interchangeability described in section 351(k)(4) of the PHS Act.

Under BsUFA III, FDA has committed to, among other things, the development of guidance documents focusing on formal meetings between FDA and sponsors or applicants of BsUFA products and topics related to interchangeable biosimilar biological products (interchangeable biosimilars or interchangeable biosimilar products) (see Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at *https://www.fda.gov/media/152279/download*). These guidance documents are not product-specific or product class-specific but rather apply across many products and product classes. In contrast, under the GDUFA science and research program, FDA conducts research in support of various regulatory science initiatives, the results of which support development of both general and product-specific guidance for industry.

As part of the BsUFA III program, FDA has updated its biosimilar action plan [2] and is revisiting how best to advance the development of new biosimilar products. FDA guidance can enhance scientific and regulatory clarity for the biosimilar product development community and, when finalized, represents FDA's current thinking on the matter.

II. Issues for Consideration and Request for Information and Comments

FDA is seeking input from industry on whether product-specific guidance outlining the development program for a particular product would be valuable to the biosimilar product development community. A model for this approach is the GDUFA science and research program that, among other things, supports the issuance of product-specific guidance documents, of which there are currently over 2,000.[3] Alternatively, FDA is seeking input on whether product class-specific guidance, which may apply more broadly to a class of products, would be valuable to the biosimilar product development community. Specifically, FDA is seeking input on the following questions:

1. Which would be more useful for accelerating biosimilar development: guidance documents that focus on a particular product (product-specific guidance), or guidance documents that are cross-cutting for a class of biosimilar products (product class-specific guidance) such as monoclonal antibodies?

2. Should FDA focus on development of guidance documents for biological products (or classes of biological products) for which there are no approved biosimilars? Or would it be useful for FDA to continue to develop guidance on biosimilar development programs even after one or more biosimilar products have been approved for that biological product or class of biological products?

Dated: July 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16405 Filed 7–24–24; 8:45 am]

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[1] See *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.*

[2] See *https://www.fda.gov/drugs/biosimilars/biosimilars-action-plan#clarity.*

[3] See the Product-Specific Guidances for Generic Drug Development web page at *https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research.

This is a hybrid meeting held in-person and virtually and is open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from *https://www.genome.gov/event-calendar/103rd-Meeting-of-National-Advisory-Council-for-Human-Genome-Research.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: September 9–10, 2024.

Closed: September 09, 2024, 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700 Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).

Open: September 09, 2024, 10:00 a.m. to 6:00 p.m.

Agenda: Report of Institute Director and Institute Staff.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).

Closed: September 10, 2024, 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700 Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid).

Contact Person: Jennifer L. Troyer, Ph.D., Director, Division of Extramural Operations, National Human Genome Research Institute, National Institutes of Health, NIH 6700 Rockledge Drive, Suite 3100, Bethesda, MD 20892, (301) 480–3565, *troyerj@mail.nih.gov.*