the effective date of re-approval. If we determine that AABB has failed to adopt, maintain, and enforce requirements that are equal to, or more stringent than, the CLIA requirements or that systemic problems exist in its monitoring, inspection, or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which AABB would be allowed to address any identified issues. Should AABB be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke AABB's deeming authority under CLIA.

Should circumstances result in our withdrawal of AABB's re-approval, we will publish a notice in the **Federal Register** explaining the basis for removing its re-approval.

VI. Collection of Information Requirements

The information collection requirements associated with the accreditation process for clinical laboratories under the CLIA program are currently OMB-approved under OMB control number 0938–0686 and expire May 31, 2025. Additionally, this notice does not impose any new or revised information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–08809 Filed 4–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5473]

Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Revised Draft Guidance for Industry; Availability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 revised draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' FDA is issuing this revised draft guidance to address questions that manufacturers, packers, distributors, and their representatives (firms) may have when developing FDA-regulated promotional labeling and advertisements (promotional communications) for prescription reference products, biosimilar products, and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act). In conjunction with the enactment of the Biosimilar User Fee Amendments of 2022 (BsUFA III), FDA agreed to publish a draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products, as described in the document titled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027.'' The revised draft guidance is consistent with this commitment and replaces the draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Questions and Answers'' issued on February 4, 2020.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2024 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–2019–D–5473 for ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' 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 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 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: Alpita Popat, Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993–0002, 301–796–1200, *CDER-OPDP-RPM@fda.hhs.gov;* or James Myers, 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 revised draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' The revised draft guidance addresses questions firms may have when developing FDA-regulated promotional communications for prescription reference products licensed under section 351(a) of the PHS Act (42 U.S.C. 262(a)) and prescription biosimilar products, including interchangeable biosimilar products, licensed under section 351(k) of the PHS Act. *Reference product,* as defined in section 351(i)(4) of the PHS Act, means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act. This guidance does not make any recommendations for nonprescription products. Unless otherwise specified, the term *biosimilar product* as used in this revised draft guidance refers to a product that is licensed under section 351(k) of the PHS Act as biosimilar to or biosimilar to and interchangeable with a reference product.

Section 351(k) of the PHS Act provides an abbreviated licensure pathway for biological products shown to be biosimilar to or biosimilar to and interchangeable with an FDA-licensed reference product. Section 351(i) of the PHS Act defines *biosimilarity* to mean ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.'' To meet the standard for *interchangeability,* an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (351(k)(4) of the PHS Act). Interchangeable biosimilar products may be substituted for the reference product without the intervention of the prescribing healthcare provider (351(i)(3) of the PHS Act).

FDA is providing this revised draft guidance to address questions firms may have when developing FDA-regulated promotional communications for prescription reference products or prescription biosimilar products, including interchangeable biosimilar products. The revised draft guidance discusses considerations for presenting data and information about reference products or biosimilar products in these promotional communications to help ensure that they are accurate, truthful and non-misleading. The revised draft guidance includes information about general requirements for the content of FDA-regulated promotional communications that apply to reference products and biosimilar products and includes more specific considerations for developing promotional communications for reference products and biosimilar products, such as:

- Identifying reference products and biosimilar products
- Presenting information from the studies conducted to support licensure of the reference product when the information is included in the FDA-approved labeling of both the reference and the biosimilar products
- Presenting data or information for a biosimilar product related to the safety or effectiveness of the biosimilar product that is not included in the FDA-approved labeling but is consistent with the FDA-approved labeling for that product (see the guidance for industry entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling: Questions and Answers'' (June 2018))
- Presenting comparisons between a reference product and its biosimilar product(s)
- Submitting promotional communications to FDA

The revised draft guidance also provides examples to illustrate some of the considerations outlined in the guidance.

This revised draft guidance replaces the draft guidance for industry ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Questions and Answers''

issued on February 4, 2020 (85 FR 6201) (2020 draft guidance). In revising this guidance, FDA considered comments received on the 2020 draft guidance and expanded the scope of the 2020 draft guidance to fulfill the BsUFA III commitment to publish draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products. Changes from the 2020 draft guidance include additional recommendations and an example for interchangeable biosimilar products. In addition, editorial changes were made to improve clarity.

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 ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in FDA's guidance entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format: Promotional Labeling and Advertising Materials for Human Prescription Drugs,'' the collections of information in 21 CFR part 314, and the collections of information resulting from submissions using Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 202.1 have been approved under OMB control number 0910–0686; the collections of information in FDA's guidance entitled ''Medical Product Communications That Are Consistent With the Food and Drug Administration Required Labeling: Questions and Answers'' have been approved under OMB control number 0910–0856; the collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303; and the collections of information relating to section 351(k) of the Public Health Service Act relating to biosimilar and interchangeable product applications have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08886 Filed 4–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0477]

Agency Information Collection Revision 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 24, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0477–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Incident Report Form.

Type of Collection: Reinstatement with Change.

OMB No.: 0990–0477.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting reinstatement of the OMB No. 0990–0477, Incident Report Form, with two new information elements on the Incident Report form: *IORG # for Reviewing IRB;* and, *Revising research policies and procedures* as a corrective action plan category, if it applies. The purpose of the Incident Report form is to facilitate organizations or institutions prompt reporting of specific human subject protection incidents to OHRP, in a simplified standardized format, as required by HHS protection of human subjects regulations at 45 CFR part 46.

ANNUALIZED BURDEN HOUR TABLE

Forms name	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Incident Report	25	1	30/60	12.5
Incident Report	25	3	30/60	37.5
Incident Report	200	5	30/60	500
Total				550