DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1954]

Classification Categories for Certain Supplements Under Biosimilar User Fee Amendments III; 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 final guidance for industry entitled ''Classification Categories for Certain Supplements Under BsUFA III.'' This guidance provides recommendations for applicants on classification categories A, B, C, D, E, and F for original and resubmitted prior approval supplements submitted to approved applications for biosimilar and interchangeable biosimilar products under the Public Health Service Act (PHS Act). The commitment letter associated with the Biosimilar User Fee Amendments of 2022 (BsUFA III) sets forth these supplement classification categories and their associated review performance goals. This guidance is intended to help applicants identify the appropriate classification category and review goal date of the supplement being submitted. This guidance finalizes and replaces the draft guidance of the same title issued on August 11, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2025.

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–2023–D–1954 for ''Classification Categories for Certain Supplements Under BsUFA III.'' 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. 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: Mustafa Ünlü, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301–796–3396; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Classification Categories for Certain Supplements Under BsUFA III.'' This guidance provides recommendations for applicants and FDA review staff on classification categories A, B, C, D, E, and F for original and resubmitted prior approval supplements (hereafter ''supplements'') submitted to approved applications under section 351(k) of the PHS Act (42 U.S.C. 262(k)). These classification categories pertain to supplements for biosimilar and interchangeable biosimilar products seeking the following:

- To update prescribing information and, if applicable, FDA-approved patient labeling (*e.g.,* Patient Package Insert, Medication Guide, Instructions for Use) with safety information that has been updated in the reference product labeling and is applicable to one or

more indications for which the biosimilar or interchangeable biosimilar product is licensed.

- To receive licensure for an additional indication.
- To remove an approved indication.
- To receive an initial determination of interchangeability.

Supplements to approved applications under section 351(k) of the PHS Act that do not meet the criteria under Categories A through F are outside the scope of this guidance.

This guidance is intended to help applicants identify the appropriate classification category and review goal date of the supplement being submitted. Section I.A. of the commitment letter associated with the BsUFA III sets forth these supplement classification categories and their associated review performance goals. The full text of the proposed BsUFA III Commitment Letter can be found on the Agency's web page ''BsUFA III: Fiscal Years 2023–2027,'' available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027*.

This guidance finalizes the draft guidance entitled ''Classification Categories for Certain Supplements Under BsUFA III'' issued on August 11, 2023 (88 FR 54626). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification that the guidance does not include recommendations for manufacturing-only supplements or for all supplements for safety-related updates to the labeling, clarification that applicants can request reconsideration of classification category with appropriate justification, and clarification that a pediatric assessment or amended initial pediatric study plan may be included in a Category D supplement. In addition, editorial changes were made to improve clarity.

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 ''Classification Categories for Certain Supplements Under BsUFA III.'' 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 OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information pertaining to the Biosimilar User Fee Program and for the submission of biologics license applications under section 351(k) of the PHS Act regarding biosimilar product applications, interchangeable biosimilar product applications, and supplemental applications have been approved under OMB control number 0910–0718. The collections of information in 21 CFR 201.56 and 201.57 for the submission of labeling have been approved under OMB control number 0910–0572. The collections of information pertaining to Medication Guides for prescription human drug and biological products have been approved under OMB control number 0910–0393. The collections of information in 21 CFR part 601 for the submission of biologics license applications, supplemental applications, and Form FDA 356h have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the 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*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5943]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Product Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 9, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0650. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tobacco Product Establishment Registration and Listing

OMB Control Number 0910–0650—Revision

This information collection supports the Food and Drug Administration (FDA, us, or we) regulations and guidance. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 921) (21 U.S.C. 387 through 21 U.S.C. 387u).

Section 905 of the FD&C Act requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' Section 905 of the FD&C Act requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services (Secretary) has delegated to the FDA Commissioner the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) their name; (2) places of business; (3) a list of all tobacco products which are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco