copy of the document. Please use the document number GUI00007079 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following table have been approved by OMB:

21 CFR part	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR).	0910–0073

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19181 Filed 9–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2787]

Biosimilar User Fee Act III Future Needs in the Development of Interchangeable Products Post-Workshop; Draft Strategy Document

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a draft strategy document titled ''BsUFA III Future Needs in the Development of Interchangeable Products Post-Workshop Strategy Document'' (Strategy Document). This draft Strategy Document is intended to summarize the discussion that occurred at the FDA public workshop, ''Advancing the Development of Interchangeable Products: Identifying Future Needs,'' held on September 19, 2025, and to describe FDA's future directions to support interchangeable biosimilar products. FDA is issuing this draft Strategy Document to fulfill a commitment FDA made in the Biosimilar User Fee Act (BsUFA) reauthorization commitment letter for fiscal years 2023 through 2027 (BsUFA III) to publish a post-workshop draft strategy document for public comment.

DATES: Submit either electronic or written comments on this draft Strategy Document by November 17, 2026 to ensure that the Agency considers your comment on this draft Strategy Document before it begins work on the final version of the Strategy Document.

ADDRESSES: You may submit either electronic or written comments 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–2025–N–2787 for ''Biosimilar User Fee Act III Future Needs in the Development of Interchangeable Products Post-Workshop; Draft Strategy Document.'' 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 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.

FOR FURTHER INFORMATION CONTACT: Sarah Ikenberry, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1128, Silver Spring, MD 20993–0002, 301–796–6893, *CDER-BiologicsBiosimilarsInquiries@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft Strategy Document titled ''BsUFA III Future Needs in the Development of Interchangeable Products Post-Workshop Strategy Document.'' In section II.D.3 of the BsUFA III commitment letter (available at *https://www.fda.gov/media/152279/download?attachment*), FDA agreed to hold a public scientific workshop on the development of interchangeable biosimilar products to help identify future needs (*e.g.,* guidance, research). FDA also agreed to issue a draft strategy document for public comment outlining the specific actions FDA will take to facilitate interchangeable biosimilar product development within 12 months following the public workshop. The public workshop was held on September 19, 2025 (90 FR 39395), with both virtual and in-person attendance, and representatives from trade associations (Association for Accessible Medicines (AAM), Pharmaceutical Research and Manufacturers of America (PhRMA), and Biosimilars Forum) provided their perspectives on future needs for development and adoption of interchangeable biosimilar products. FDA speakers from the Center for Drug Evaluation and Research discussed scientific topics related to analytical data considerations, user interface and human factors considerations, and other considerations to facilitate development of interchangeable biosimilar products. The draft Strategy Document summarizes the discussion that occurred during the workshop as well as comments received in the public docket. The major themes identified during the workshop and in comments submitted to the docket included timely communication of new scientific and policy developments, challenges with user interface development and human factors analyses, and approaches to interchangeability that follow the evolving science. Over the last 5 years, the development and approval of interchangeable biosimilar products have advanced considerably. FDA's future efforts will focus on continuing to follow the evolving science, providing educational resources for healthcare providers and patients, and helping to ensure that stakeholders have confidence in the safety and effectiveness of interchangeable biosimilar products.

II. Electronic Access

The draft Strategy Document is available on the FDA web page for the public workshop at *https://www.fda.gov/industry/fda-public-workshop-future-needs-development-interchangeable-products-09192025#event-information.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19166 Filed 9–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–7233]

Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; 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 (GFI) #298 (VICH GL62) titled ''Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products.'' This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance contributes to the international harmonization of methods used for the target animal safety (TAS) evaluation of veterinary monoclonal antibody products (VMAPs) and aids in preparing and conducting VMAP TAS studies under laboratory and field conditions. A harmonized standard is intended to aid in development of mutually acceptable VMAP TAS programs.

DATES: Submit either electronic or written comments on the draft guidance by November 17, 2026 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–2026–D–7233 for ''Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; Draft 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, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your