and Topical Delivery Systems for ANDAs.'' This guidance finalizes the draft guidance (Revision 2), which was announced in the **Federal Register** on April 13, 2023 (88 FR 22456). FDA received no comments on the revised draft guidance (Revision 2) and, thus, no comments were considered before publication of this guidance.

The guidance provides recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS. Depending on the objectives of a generic TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only, or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and BE with PK endpoints). FDA recommends that applicants consult this guidance in conjunction with any relevant product-specific guidances for industry when considering the design and conduct of studies that may be appropriate to support the BE of a proposed generic TDS product to its reference listed drug and/or reference standard product. FDA also recommends that an applicant who seeks to use an alternative approach to FDA's recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS contact the Agency to discuss the proposed alternative approach to evaluate adhesion performance for that particular drug product.

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 ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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 final 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 21 CFR part 314 relating to the submissions of abbreviated new drug applications have been approved under OMB control number 0910–0001.

III. Electronic Access

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

[FR Doc. 2026–15613 Filed 7–31–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–4272]

Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts.'' This draft guidance is intended to help applicants develop container closure systems and device constituent parts for proposed biosimilar and interchangeable biosimilar products. This draft guidance expands on and clarifies the Agency's recommendations and expectations regarding the development of delivery devices and container closure systems described in Q.I.4 of the guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act'' and the guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' for biosimilar and interchangeable biosimilar products, respectively.

DATES: Submit either electronic or written comments on the draft guidance by October 2, 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. [insert docket number xxxxx] for ''Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts.'' 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. 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: Mustafa Ünlü, Center for Drug Evaluation and Research (HF–22), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301–796–3396, *CDER-BiologicsBiosimilarsInquiries@fda.hhs.gov;* 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 draft guidance for industry entitled ''Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts.'' As part of the negotiations relating to the reauthorization of the Biosimilar User Fee Act (BsUFA), as described in ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures for Fiscal Years 2023 Through 2027'' (BsUFA III goals letter), FDA agreed to issue guidance on ''considerations for developing presentations, container closure systems, and device constituent parts for proposed interchangeable biosimilar biological products.'' This draft guidance expands on and clarifies the Agency's recommendations and expectations regarding the development of delivery devices and container closure systems described in Q.I.4 of the guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act'' issued on September 20, 2021 (86 FR 52154) (the Biosimilar Q&As) and the guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' issued on May 14, 2019 (84 FR 21342) (the Interchangeability guidance) for biosimilar and interchangeable biosimilar products, respectively. When this draft guidance is finalized, the Agency intends to update section VIII of the Interchangeability guidance, ''Considerations for Developing Presentations for Proposed Interchangeable Products,'' and to remove Q.I.4 of the of the Biosimilar Q&As.

Section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)) provides an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product. Section 351(k) of the PHS Act sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable biosimilar product. In this draft guidance, FDA outlines its recommendations for the development of container closure systems and device constituent parts for biosimilar and interchangeable biosimilar products.

Expectations regarding product quality considerations for container closure systems and devices are generally the same for proposed biological products submitted in a marketing application under section 351(a) of the PHS Act as for proposed biosimilar and interchangeable biosimilar products submitted in a marketing application under section 351(k) of the PHS Act. The draft guidance provides a high-level summary of product quality recommendations that are captured across multiple FDA guidances.

The draft guidance also describes considerations for the evaluation of the user interface of the presentations of proposed biosimilar and interchangeable biosimilar combination products through comparative analyses to determine if potential differences from the reference product warrant collecting additional information to support approval of the proposed combination product as biosimilar to or interchangeable biosimilar with its reference product.

In addition, the draft guidance explains the challenges that may arise when seeking licensure of an interchangeable biosimilar combination product in a different presentation than its reference product and encourages discussions with the Agency early during the development of such products.

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 ''Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 21 CFR part 312 regarding sponsor requests to FDA related to the submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in section 351(a) of the PHS Act and part 601 (21 CFR part 601)

relating to the submission of a biologics license application have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and part 601 relating to the submission of biosimilar applications and biosimilar user fee applications have been approved under OMB control number 0910–0718. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice requirements have been approved under OMB control number 0910–0139. 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.

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.

[FR Doc. 2026–15630 Filed 7–31–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3546]

Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; 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 titled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This revised draft guidance provides recommendations for the design and conduct of studies to evaluate the in vivo skin irritation (and sensitization, if applicable) potential of a proposed transdermal or topical delivery system (collectively referred to as TDS). The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA). The revised draft guidance is intended to clarify FDA's recommendations and expectations related to in vivo skin irritation and in vivo combined skin irritation and sensitization studies. This draft guidance replaces the draft guidance ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs'' (April 2023).

DATES: Submit either electronic or written comments on the draft guidance by October 2, 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–2018–D–3546 for ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' 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