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]

BILLING CODE 4164–01–P

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Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry titled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This revised draft guidance provides recommendations for the design and conduct of studies to evaluate the in vivo skin irritation (and sensitization, if applicable) potential of a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 The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA). The revised draft guidance is intended to clarify FDA's recommendations and expectations related to in vivo skin irritation and in vivo combined skin irritation and sensitization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 This draft guidance replaces the draft guidance ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs'' (April 2023).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

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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 guidance revises the draft guidance of the same name that was published in the **Federal Register** on April 13, 2023 (83 FR 50945).

The components and composition of a TDS formulation, including the nature of the drug substance and/or the occlusivity of the TDS materials, in conjunction with other factors such as the environmental humidity or the condition of the skin, may have the potential to irritate the skin or lead to a sensitization reaction. Such reactions can be unpleasant to the patient and may affect patient compliance, skin permeability, and/or adhesion of the TDS to the skin. The collective consequence of these potential effects could create uncertainty about the resulting drug delivery profile and the rate and extent of drug absorption from the TDS. Therefore, when appropriate, applicants should perform a comparative assessment of the test (T) and reference (R) TDS products using an appropriately designed skin irritation (or combined irritation and sensitization) study with human subjects to demonstrate that the potential for a skin irritation or sensitization reaction with the T TDS is no worse than the reaction observed with the R TDS.

This revised draft guidance (Revision 2) provides the following updates to the last revised draft guidance (Revision 1) from April 2023:

(1) Clarifies recommendations for the design and conduct of studies to evaluate the in vivo skin irritation (and sensitization, if applicable) potential of a proposed TDS.

(2) Clarifies when an in vivo study to assess the sensitization potential of a TDS product may not be needed.

The recommendations in this revised draft guidance relate to studies submitted in support of an ANDA. The Agency is seeking comments on the recommendations reflected in the revised draft guidance announced in this notice. In addition, FDA invites comments on the scoring scales and any alternative approaches, including those recommended by international regulatory agencies, that may have been used for the comparative assessment of the irritation/sensitization potential for proposed generic TDS products. FDA also specifically invites comments regarding the comparative assessment of sensitization itself, *i.e.,* whether there are clinical scenarios where a comparative sensitization assessment may be uninformative when conducted in addition to a comparative irritation assessment.

This revised 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 ''Assessing the Irritation and Sensitization Potential of 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. 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 314 relating to the submission of abbreviated new drug applications, including the design and conduct of studies and the submission of study data, as well as the collections of information relating to good clinical practice, have been approved under OMB control number 0910–0001. The collections of information for controlled correspondence and meetings related to generic drug development are approved under OMB control number 0910–0727.

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/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

Health Resources and Services Administration

Notice Regarding 340B Rebate Model Pilot Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA), which administers the 340B Drug Pricing Program (340B Program), is issuing this Notice to announce the availability of a revised 340B Rebate Model Pilot Program (Pilot). The Pilot provides a rebate mechanism through which qualifying drug manufacturers may effectuate the 340B ceiling price for certain drugs sold to covered entities. Consistent with HRSA's longstanding statutory authority, rebates will be used instead of upfront discounts.

HRSA issued a Request for Information (RFI) [1] to gather input from interested parties regarding the potential use of rebates to effectuate the ceiling price under the 340B Program, including the standards and procedures that should govern the approval of manufacturer rebate plans and the impacts on all stakeholders. After carefully considering all comments from interested parties and different policy alternatives, HRSA is announcing this Pilot, which will implement a rebate approach for a limited set of drugs, and which builds on established and successful rebate programs.

This Notice is effective immediately as published, unless revised by a future notice. HRSA reserves the right to issue revisions or addenda to this Notice at a later date.

[1] *Request for Information* (91 FR 7287) (Feb. 17, 2026), available at *https://www.federalregister.gov/documents/2026/02/17/2026-03042/request-for-information-340b-rebate-model-pilot-program.*