• 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: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This revised draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018 (83 FR 50942). FDA received five comments on the revised draft guidance (Revision 1), which were considered before publication of this revised draft guidance (Revision 2).

This revised draft guidance (Revision 2) provides recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS submitted in support of an ANDA. Depending on the objectives of a 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 revised draft guidance (Revision 2) 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.

Specifically, in response to the comments received from industry, FDA is clarifying the following components of the guidance. When recording measurements of TDS adhesion, applicants may use appropriate methods (*e.g.,* a trained visual assessment and/or dot matrix templates) and are encouraged to explore the use of alternative scales (other than the five-point adhesion scale) to estimate the percentage of the entire TDS surface area that is adhered to the skin. At each adhesion assessment time point, applicants should also record photographic evidence showing the extent of TDS adhesion to the skin. Because percent adhesion can span a range and yet be classified as a single score, the photographic evidence can be used to support the visual observation of the percent adhesion reported at each time point and is not intended to be used for automated or photometric analysis at this time. Additional clarity is also provided related to the statistical analysis of data. Finally, FDA 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 to contact the Agency to discuss the proposed alternative approach to evaluate adhesion performance for that particular drug product.

This revised draft guidance (Revision 2) is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent 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 revised draft guidance (Revision 2) contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07770 Filed 4–12–23; 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 entitled ''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 (I/S) 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 I/S studies. This guidance revises the October 2018 draft guidance entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.''

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This guidance revises the draft guidance entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs'' that was published in the **Federal Register** on October 10, 2018 (83 FR 50945). FDA received eight comments on the draft guidance, which were considered before publication of this revised draft guidance.

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 uncertainty about 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 I/S 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 provides the following updates to the original draft guidance:

(1) Clarifies recommendations for the design and conduct of studies to evaluate the in vivo skin I/S 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.

(3) Provides guidance to applicants intending to utilize alternative scoring scales or alternative approaches to compare irritation and sensitization between the T and R TDS.

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 I/S 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.

II. Paperwork Reduction Act of 1995

While this revised draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 relating to the submission of abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information relating to good clinical practice have been approved under OMB control number 0910–0843.

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.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07769 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0379 Revision]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for the Health Resources and Services Administration

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 12, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for HRSA—OMB No. 0915–0379—Revision

Abstract: The purpose of information collections under this generic umbrella ICR package is to allow HRSA to continue collecting feedback from members of the public for HRSA to use when developing new questions, questionnaires, and tools; pilot/pre-test instruments to be deployed by HRSA; and to identify problems in instruments currently in use.

This generic clearance is limited to data collection for the development or revision of HRSA tools and data collection instruments, as well as reports for internal decision-making and development purposes. Information collected under this generic clearance will not be used for data collection, reports, or policy documents to be released to the public. It is anticipated that data collection approved under this generic clearance will rely heavily on qualitative techniques and not the collection of numerical data. In general, these activities are not designed to yield results that meet generally accepted standards of statistical rigor but designed to obtain information to develop clearer and more effective and efficient data collection tools that will yield more accurate results and decrease public non-response. The forms submitted under this generic clearance will be voluntary, low-burden, and uncontroversial.

HRSA originally developed this generic umbrella ICR to support similar needs across HRSA's bureaus and offices as reflected in their specific activities informed by their specific authorizing statutes. The purpose is to collect qualitative data from small groups of people in response to short questionnaires, using questions posed on HRSA's website, through focus groups and individual interviews of HRSA staff and members of the public. The abbreviated clearance process of the generic clearance helps ensure timely data gathering on current issues HRSA is addressing (*e.g.,* allows program offices to gather a suitable pool of