



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-2323]

Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.” Transdermal delivery systems are designed to deliver a drug across the skin and into systemic circulation, whereas topical delivery systems are designed to deliver the drug to local tissue. There is pharmaceutical and other stakeholder interest in the development of new transdermal and topical products, and this guidance provides recommendations on the clinical assessment of adhesion for such products that will be submitted as new drug applications (NDAs) or supplemental new drug applications. This guidance provides additional study design and methodology recommendations on conducting in vivo adhesion studies. This guidance takes these developments into consideration. When final, this draft guidance will expand upon the recommendation for in vivo adhesion studies in section V., Special Topics, subsection A., Product Adhesion Considerations, in the draft guidance for industry Transdermal and Topical Delivery Systems – Product Development and Quality Considerations issued on November 21, 2019.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2020-D-2323 for "Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug

Applications.” 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: Margaret Kober, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5376, Silver Spring, MD, 20993-0002, 301-796-0934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.” This draft guidance provides recommendations on the clinical assessment of the adhesive properties of topical and transdermal delivery systems (collectively referred to as TDS) intended for submission in an NDA or supplemental NDA. The amount of drug delivered into and through the patient’s skin from a TDS is dependent, in part, on the ability of the TDS to remain in direct contact with the skin (adhesive properties). Adhesive properties are clinically important as a loss of TDS adhesion during wear can reduce the amount of drug delivered to the patient, potentially compromising effectiveness. Additionally, partial or full detachment of a TDS from a patient’s skin may result in unintentional exposure of the drug to others, potentially compromising safety. This draft guidance includes key considerations for the design of the TDS adhesion clinical study, including the selection of endpoints and FDA’s current thinking on acceptable adhesion performance in the in vivo setting.

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 “Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications” and will supersede in vivo recommendations in section V., Special Topics in the draft guidance for industry “Transdermal and Topical Delivery Systems--Product Development and Quality Considerations” issued on November 21, 2019 (84 FR 64319). 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. 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, and the collections of information for the electronic submission of drug establishment registration and drug listing information have been approved under OMB control number 0910-0045.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: June 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.