4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2020-D-0043]

Contact Dermatitis from Topical Drug Products for Cutaneous Application: Human Safety Assessment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment." This draft guidance provides recommendations for the characterization, during product development, of local safety of topical drug products regarding the risk for contact dermatitis. These recommendations are specifically directed to development of topical new drug products intended for cutaneous application.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-0043 for "Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment." 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.

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: Jennifer Harmon, Center for Drug Evaluation and Research (HFD-540), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5239, Silver Spring, MD 20993; 240-402-4880.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment."

Historically, FDA requested sponsors of new topical drug products to characterize local safety with regard to cutaneous irritation, sensitization, phototoxicity, and photoallergy (the latter two only for products that absorb ultraviolet radiation at relevant wavelengths) through the conduct of dedicated "dermal safety studies." These studies were conducted in healthy volunteers by repeated application of the drug product under occlusion on the skin of the back or upper arm. The studies are considered provocative in that the test condition of occlusion is used

to evoke the adverse reaction at a greater rate than might be observed under labeled conditions of use.

The Division of Dermatology and Dental Products (DDDP) became concerned that these provocative studies, conducted under augmented conditions, were not informative for drug development, did not provide information that was useful for labeling, and induced adverse reactions in study subjects that might result in permanent harm. DDDP convened a scientific workshop in September 2018 during which outside experts provided input on the utility of these studies for development of new topical drugs. The consensus of the workshop was that the dedicated dermal safety studies, previously requested by FDA, were not needed to evaluate local cutaneous safety of topical new drug products.

DDDP intends to publish this draft guidance to inform sponsors of new topical drug products intended for cutaneous application of our recommendations for evaluating local (cutaneous) safety of topical drug products with regard to contact dermatitis. These recommendations will be specifically directed to developing topical new drug products; the draft guidance will not address over-the-counter drugs under monograph, generic drugs, or nondrug cosmetic products or ingredients.

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 "Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment." 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

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

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: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-04753 Filed: 3/6/2020 8:45 am; Publication Date: 3/9/2020]