4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2582]

Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the following 1-day public workshop entitled "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation." The purpose of the public workshop is to provide a forum to discuss the current state and future directions of the collection of human data on the potential skin toxicity with the use of medications applied topically. The workshop will review current approaches to the collection of human data during the clinical development of topical drug products. The workshop will also address the impact of human skin toxicity studies on drug labeling and consider alternative approaches to providing information about skin toxicity.

DATES: The public workshop will be held on September 10, 2018, from 8:30 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by October 10, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver

Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 10, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-N-2582 for "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Tisha Washington, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1019, tisha.washington@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop entitled "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation" to discuss the current state and

future directions of the collection of human data on the potential skin risks from use of topical drug products, including irritancy, sensitization, phototoxicity, and photoallergenicity.

II. Topics for Discussion at the Public Workshop

The morning session of the workshop will focus on review and discussion of current approaches for the collection of human skin toxicity data, limitations of these approaches, and their impact on labeling of topical drug products. The afternoon session of the workshop will be a panel discussion by individuals with different perspectives about alternative approaches to provide information about skin toxicity. Thirty minutes of the afternoon session will be allocated to an open public hearing. The Agency encourages health care providers, industry representatives, and other interested persons to attend this public workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website by September 4, 2018: https://www.eventbrite.com/e/fda-public-workshop-human-dermal-safety-testing-for-topical-drug-products-tickets-47483161414. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone, and intended attendance method--in person or by webcast. You may also indicate if you wish to present at the public comment session (see *Requests for Oral Presentations*). For those unable to attend in person, FDA will provide a live webcast of the workshop.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 5 p.m. Eastern Time, September 4, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Seating will be available on a first-come,

first-served basis. If time and space permit, onsite registration on the day of the workshop will be provided beginning at 8:15 a.m. Eastern Time; FDA will let the public know whether onsite registration is available before the day of the public workshop.

An agenda for the workshop and any other background materials will be made available 5 days before the workshop at https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm.

If you need special accommodations due to a disability, please contact Tisha Washington, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1019, tisha.washington@fda.hhs.gov no later than September 4, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present at the public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 5, 2018. All requests to make oral presentations must be received by the close of registration on September 4, 2018. If selected for presentation, any presentation materials must be emailed to Tisha Washington (see FOR FURTHER INFORMATION CONTACT) no later than close of business, September 6, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the following web page 5 days before the workshop at: https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm.

Dated: August 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-17130 Filed: 8/9/2018 8:45 am; Publication Date: 8/10/2018]