4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0275]

Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; 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 or Agency) is announcing the following public workshop entitled "Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions." The purpose of the workshop is to bring stakeholders together to discuss the scientific basis of morphine milligram equivalents (MMEs) with the goals of providing an understanding of the science and data underlying existing MME calculations for opioid analgesics, discussing the gaps in these data, and discussing future directions to refine and improve the scientific basis of MME applications.

DATES: The public workshop will be held virtually and via webcast on June 7 and 8, 2021, from 9 a.m. to 5 p.m. Eastern Time each day. Submit either electronic or written comments on this public workshop by August 9, 2021. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this public workshop via an online teleconferencing platform.

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 August 9, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 9, 2021. 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-2021-N-0275 for "Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; 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, 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 laws. 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.

FOR FURTHER INFORMATION CONTACT: Kimberly Compton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3168, Silver Spring, MD 20993-0002, 301-796-1191, kimberly.compton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Opioid analgesics vary in analgesic efficacy and potential for harm. MMEs or other similar conversion factors are used often to quantify potency across opioids, usually compared to oral morphine. MME tables were originally developed as an adjunct to clinical judgment to inform starting doses when switching patients between different opioid analgesics. However, MMEs are increasingly being used to indicate abuse and overdose potential and to set thresholds for prescribing and dispensing of opioid analgesics. FDA is convening this public workshop to discuss the current landscape and science underlying MMEs and their uses.

II. Topics for Discussion at the Public Workshop

This public workshop will provide: (1) an overview of the landscape of MMEs, starting with a historical perspective of how MMEs were originally developed and intended to be used; (2) the data informing published resources on MMEs; (3) the development and intended use of commonly-referenced sources, such as the Centers for Disease Control and Prevention's resources; (4) the current uses of MMEs and gaps in knowledge; and (5) future directions to refine and improve the scientific basis of MME applications.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: https://morphinemilligramequivalent.eventbrite.com. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free.

If you need special accommodations due to a disability, please contact Kimberly Compton (see FOR FURTHER INFORMATION CONTACT) no later than May 17, 2021.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. Submit a brief statement of the topic you wish to address and the names and addresses of proposed participants. 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. All requests to make oral presentations must be received by May 24, 2021. 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 May 31, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled public comment session, FDA may conduct a lottery to determine the speakers for the scheduled public comment session. If selected for presentation, any presentation materials must be emailed to Kimberly Compton (see FOR FURTHER INFORMATION CONTACT) no later than June 3, 2021. 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 be webcast. Additional information will be made available regarding accessing the webcast before the public workshop at https://morphinemilligramequivalent.eventbrite.com and at https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and. All other meeting materials, including agenda, will be available before the workshop at https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and.

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 (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and.

Dated: April 12, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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