4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2903]

Data and Methods for Evaluating the Impact of Opioid Formulations With Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities; Public Workshop; Issues Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled "Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities." The purpose of the public workshop is to host a scientific discussion with expert panel members and interested stakeholders about the challenges in using the currently available data and methods for assessing the impact of opioid formulations with properties designed to deter abuse on opioid misuse, abuse, addiction, overdose, and death in the postmarket setting. The goal of this meeting is to discuss ways to improve the analysis and interpretation of existing data, as well as to discuss opportunities and challenges for collecting and/or linking additional data to improve national surveillance and research capabilities in this area. To assist in the workshop discussion, FDA is making available an issues paper that provides a brief overview of the currently available data resources used for evaluating the impact of opioid formulations with properties designed to deter abuse; summarizes some of the key methodological issues in this area; and outlines the issues that we would like to discuss during

the upcoming workshop, including enhancing existing resources, applying new methodology, and creating new resources.

DATES: The public workshop will be held on July 10 and 11, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by September 11, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2017. 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. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301-589-0800.

You may submit comments 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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2017-N-2093 for "Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse Properties in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities; Public Workshop; Issues Paper; Request for Comments." Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cynthia Kornegay, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2456, Silver Spring, MD, 20993-0002, 301-796-0187, Cynthia.Kornegay@fda.hhs.gov; or Cherice Holloway, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4466, Silver Spring, MD, 20993-0002, 301-796-4909, Cherice.Holloway@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In this 2-day public workshop, FDA plans to host a scientific discussion with expert panel members and interested stakeholders about the challenges in using the currently available data and methods for assessing the impact of opioid formulations with properties designed to deter abuse on opioid misuse, abuse, addiction, overdose, and death in the postmarket setting. The goal of this meeting is to discuss ways to improve the analysis and interpretation of existing data, as well as to discuss opportunities and challenges for collecting and/or linking additional data to improve national surveillance and research capabilities in this area.

II. Topics for Discussion at the Public Workshop

FDA has developed an issues paper entitled "Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting." This issues paper (1) provides a brief overview of the currently available data resources used for evaluating opioid formulations with properties designed to deter abuse; (2) summarizes some of the key methodological issues in this area; and (3) outlines the issues we would like to discuss during the upcoming workshop, including modifying existing resources, applying new methodology, and creating new resources. The issues paper can be found on the Internet at https://www.fda.gov/Drugs/NewsEvents/ucm540845.htm.

III. Participating in the Public Workshop

Registration: To register to attend the public workshop, "Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities," in person or virtually via Webcast, please contact Cherice Holloway at cherice.holloway@fda.hhs.gov by June 26, 2017. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by June 26, 2017. 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. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Cherice Holloway at cherice.holloway@fda.hhs.gov no later than Friday, June 30, 2017.

Public Participation in Scientific Workshop: Time will be provided during the discussion of each agenda topic for audience participants to provide comments if desired. Comments should be specific to the discussion topic, and the time provided will be at the discretion of the session chair.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Additional information about accessing the Webcast will be made available at least 2 days prior to the public workshop at: https://www.fda.gov/Drugs/NewsEvents/ucm540845.htm.

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 Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at https://www.fda.gov/Drugs/NewsEvents/ucm540845.htm.

Dated: June 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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