



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5897]

Packaging, Storage, and Disposal Options to Enhance Opioid Safety--Exploring the Path Forward; 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, the Agency, or we) is announcing the following public workshop entitled “Packaging, Storage, and Disposal Options To Enhance Opioid Safety--Exploring the Path Forward.” The purpose of this 2-day public workshop is to host a scientific discussion with experts and seek input from interested stakeholders regarding the role of packaging, storage, and disposal options within the larger landscape of activities aimed at addressing abuse, misuse, or inappropriate access of prescription opioid drug products (opioids); guiding principles and considerations for the design of packaging, storage, and disposal options for opioids; integrating packaging, storage, and disposal options into existing health care and pharmacy systems, including both open and closed health care systems (e.g., a closed system such as the U.S. Department of Veterans Affairs); data needs and how to address challenges in assessing the impact of packaging, storage, and disposal options in both the premarket and postmarket settings; and ways in which FDA could encourage the development and assessment of packaging, storage, and disposal options for opioids that have the potential to enhance opioid safety.

DATES: The public workshop will be held on December 11 and 12, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by February 12, 2018. 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. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 12, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 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-2017-N-5897 for “Packaging, Storage, and Disposal Options To Enhance Opioid Safety--Exploring the Path Forward.” 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: Irene Z. Chan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD, 20993-0002, 301-796-3962, Irene.Chan2@fda.hhs.gov; or Michelle Eby, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4422, Silver Spring, MD, 20993-0002, 301-796-4714, Michelle.Eby@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is deeply concerned about the widespread epidemic of opioid abuse, dependence, and overdose in the United States. FDA believes packaging, storage, and disposal options have the potential to enhance the safety of legally prescribed opioids. The development of such options is an important component of a multi-pronged approach to addressing the current opioid epidemic.

FDA is exploring a scientific framework that supports and encourages the development of packaging, storage, and disposal options that can reduce or deter misuse, abuse, or inappropriate access to opioids, while allowing for the safe use of opioids by patients who need them. FDA will need to define the specific problems that packaging, storage, and disposal options could most effectively address; the guiding scientific principles to consider for the design and evaluation of these options; and the types of data most useful for evaluating them.

The Duke-Margolis Center for Health Policy previously convened an expert workshop on June 1, 2017, to begin examining the potential role of packaging, storage, and disposal options in enhancing opioid safety and deterring misuse, abuse, and inappropriate access. This workshop provided a forum for discussing (1) the role of packaging, storage, and disposal options in addressing factors that enable opioid abuse and misuse or inappropriate access; (2) the current range of existing packaging, storage, and disposal options; (3) approaches to evaluating the impact of packaging, storage, and disposal options on misuse and abuse or inappropriate access of opioids; and (4) considerations for integrating the use of packaging, storage, and disposal options into existing health care and pharmacy systems. Following the June 1, 2017, Duke-

Margolis Center for Health Policy expert workshop, an issues paper was developed.¹ While the expert workshop and subsequent issues paper were supported through a cooperative agreement with FDA, the views expressed in the accompanying documents are those of the participants in attendance of that expert workshop, and do not necessarily reflect the official positions and policies of the Department of Health and Human Services, or imply endorsements by the U.S. Government or other organizations.

II. Topics for Discussion at the Public Workshop

In this 2-day public workshop, FDA plans to explore the appropriate path forward by hosting a scientific discussion with experts and seeking input from interested stakeholders. Further discussion is needed regarding (1) the role of packaging, storage, and disposal options within the larger landscape of activities aimed at addressing opioid abuse, misuse, or inappropriate access; (2) guiding principles and considerations for the design of packaging, storage, and disposal options for opioids; (3) integrating packaging, storage, and disposal options into existing health care and pharmacy systems, including both open and closed health care systems (e.g., a closed system such as the U.S. Department of Veterans Affairs); (4) data needs and how to address challenges in assessing the impact of packaging, storage, and disposal options in both the premarket and postmarket settings; and (5) ways in which FDA could encourage the development and assessment of packaging, storage, and disposal options for opioids that have the potential to enhance opioid safety.

Participants will include individuals from a broad set of Federal, State, and private and public stakeholders who are working on the challenges of improving pain management while addressing the opioid abuse epidemic. Public participation and comment is encouraged.

¹ <https://healthpolicy.duke.edu/events/exploring-packaging-storage-and-disposal-solutions-enhance-opioid-safety>.

III. Participating in the Public Workshop

Registration: To register for the public workshop, “Packaging, Storage, and Disposal Options to Enhance Opioid Safety--Exploring the Path Forward,” please visit the following website to register: <https://nakamotoevents.wufoo.com/forms/pads-task-force-public-meeting/>. 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 December 1, 2017, midnight Eastern Time. 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 workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Michelle Eby at Michelle.Eby@fda.hhs.gov no later than December 4, 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 will be made available regarding accessing the webcast 2 days prior to the public workshop at <https://www.fda.gov/Drugs/NewsEvents/ucm571797.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 Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm571797.htm>.

Dated: October 11, 2017.

Anna K. Abram,

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

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