4164-01-P

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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice announcing the public workshop entitled "Packaging, Storage, and Disposal Options To Enhance Opioid Safety--Exploring the Path Forward" that appeared in the *Federal Register* on October 31, 2017, and was held on December 11-12, 2017. That notice requested comments by February 12, 2018; FDA is extending the comment period until March 16, 2018, in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the public workshop "Packaging, Storage, and Disposal Options To Enhance Opioid Safety--Exploring the Path Forward" published October 31, 2017 (82 FR 50429). Submit either electronic or written comments by March 16, 2018.

ADDRESSES: 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 March 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of March 16, 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; Public Workshop; Request for Comments." 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.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:

In the *Federal Register* of October 31, 2017 (82 FR 50429), FDA published a notice announcing a public workshop entitled "Packaging, Storage, and Disposal Options to Enhance Opioid Safety--Exploring the Path Forward," which was held on December 11-12, 2017. That notice requested comments on 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; 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. The notice requested comments by February 12, 2018; FDA is extending the comment period until March 16, 2018. The Agency believes this extension allows adequate time for interested persons to submit comments.

Dated: February 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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