



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2896]

Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the public meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products that was announced in the Federal Register on October 6, 2016. In that Federal Register notice, FDA requested comments on the approach to testing FDA recommended in its draft guidance “General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products” and FDA’s efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. We are taking this action 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 Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products published October 6, 2016 (81 FR 69532). Submit either electronic or written comments by January 3, 2017.

ADDRESSES: 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-2016-N-2896 for "Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug

Products; Extension of Comment Period.” 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 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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: Michelle Eby, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6184, Silver Spring, MD 20993, 301-796-4714, Michelle.Eby@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 6, 2016 (81 FR 69532), FDA published a notice announcing a public meeting and requesting comments on the approach to testing FDA recommended in its draft guidance “General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products”¹ and FDA’s efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. The comment period ends on December 1, 2016. Because the Agency has received requests for an extension to allow interested persons additional time to submit comments, FDA is extending the comment period until January 3, 2017.

Additional comments specific to the draft guidance “General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products” should be submitted to the docket for the draft guidance (FDA-2016-D-0785) in lieu of, or in addition to, the docket for the public meeting. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 1, 2016. Other comments should be submitted to this docket by January 3, 2016. FDA has committed to taking steps to address the epidemic of opioid abuse transparently and in close cooperation with stakeholders and will provide other opportunities to comment, as appropriate. For example, FDA intends to issue a general guidance for public

¹ <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm492172.pdf>

comment describing the Agency's recommendations for standardized in vitro testing to evaluate purported abuse-deterrent properties and considerations for a potential applicant as it develops an abuse-deterrent formulation of an opioid drug product.

Dated: November 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-29097 Filed: 12/2/2016 8:45 am; Publication Date: 12/5/2016]