4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1092]

Over-the-Counter Monograph User Fees: Reopening of Comment Period; Stakeholder Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period; stakeholder meeting.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the document that announced a public meeting in the Federal Register of May 11, 2016. In the document, FDA invited public comment as the Agency considers a user-fee program for nonprescription (over-the-counter or OTC) monograph drugs. FDA will hold a Webinar for stakeholders on September 6, 2016. This Webinar is intended to be a followup to the June 10, 2016, public meeting on this topic and to provide stakeholders with a status update on the process of FDA and industry discussions that began in July 2016.

DATES: Submit either electronic or written comments by October 6, 2016. FDA will hold a Webinar for stakeholders on Tuesday, September 6, 2016, from 10:30 a.m. to 12 p.m EDT.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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-1092 for "Over-the-Counter Monograph User Fees: Reopening of Comment Period; Stakeholder Meeting." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://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 http://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 http://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: Amy Bertha, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1647, email: OTCMonographUserFeeProgram@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is reopening until October 6, 2016, the comment period for the document that announced a public meeting in the Federal Register of May 11, 2016 (81 FR 29275). In the document, FDA invited public comment as the Agency considers a user-fee program for nonprescription (over-the-counter or OTC) monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. A public meeting on this topic was held on June 10, 2016, and interested persons were given until July 11, 2016, to submit comments. To ensure that all interested persons have sufficient opportunity to share their views on a potential OTC monograph user-fee program, FDA is reopening the comment period until October 6, 2016.

FDA will hold a Webinar for stakeholders on September 6, 2016. This Webinar is intended to be a followup to the June 10, 2016, public meeting and provide stakeholders with a status update on the process of FDA and industry discussions that began in July 2016. Meeting minutes from these discussions can be found at: http://www.fda.gov/omuf. Additional background information on OTC monograph drugs (such as how OTC drugs can be marketed, the differences between marketing through approved applications and marketing under the monographs), factors FDA considers important in developing a user-fee program, and the

questions FDA asked the public to consider and provide input, can be found in the Federal Register document from the June 10, 2106, public meeting (https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments). The meeting transcript, meeting recording, and presentations from the June 10, 2016, public meeting, which can serve as further background information, can be found at: http://www.fda.gov/Drugs/NewsEvents/ucm499390.htm.

II. Stakeholder Meeting Participation

FDA is seeking participation at the Webinar by stakeholders, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. Participating in the Webinar is free. The Webinar format will include presentations by FDA staff and an opportunity for stakeholders to ask questions. If you wish to attend the Webinar, FDA asks that you please register through Eventbrite by Tuesday, August 30, 2016 (https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-stakeholder-meeting-tickets-26751882601). FDA will email the registered attendees a URL to join the Webinar at least 1 day before the meeting.

Dated August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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