FOR FURTHER INFORMATION CONTACT: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283, *michael.ryan@fda.hhs.gov; or* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A premarket notification (510(k)) is required when a legally marketed device subject to 510(k) requirements is about to be significantly changed or modified in design, components, method of manufacture, or intended use. Significant changes or modifications are those that could significantly affect the safety or effectiveness of the device, or major changes or modifications in the intended use of the device (21 CFR 807.81(a)(3)). This guidance, when finalized, will aid manufacturers of medical devices who intend to modify a 510(k)-cleared device or a preamendments device subject to 510(k) (*i.e.,* ''existing devices'') during the process of deciding whether the modification exceeds the regulatory threshold of 21 CFR 807.81(a)(3) for submission and clearance of a new 510(k).

This guidance, when finalized, will supersede the original ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' issued on January 10, 1997. That guidance provided the Agency's interpretation of whether the modification exceeds the regulatory threshold of 21 CFR 807.81(a)(3), with principles and points for manufacturers to consider in analyzing how changes in devices may affect safety or effectiveness and determining whether a new 510(k) must be submitted for a particular type of change. This draft guidance preserves the basic format and content of the original, with updates to add clarity. The added clarity is intended to increase consistent interpretations of the guidance by FDA staff and manufacturers.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device'' to aid manufacturers of medical devices who intend to make software changes to an existing device during the process of deciding whether the software modification exceeds the regulatory threshold of 21 CFR 807.81(a)(3) for submission and clearance of a new 510(k).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on when to submit a 510(k) for a change to an existing device. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500054 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485.

Dated: *August 2, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18713 Filed 8–5–16; 8:45 am]

BILLING CODE 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.

[FR Doc. 2016–18717 Filed 8–5–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1805]

Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the completion of the target of the goal established to address the Center for Devices and Radiological Health's (CDRH) 2014–2015 Strategic Priority ''Strike the Right Balance Between Premarket and Postmarket Data Collection.'' To achieve this Strategic Priority, CDRH established a goal to assure the appropriate balance between premarket and postmarket data