4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2017-N-5319]

Devices Proposed for a New Use with an Approved, Marketed Drug; Public Hearing; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is reopening the comment period for the document published in the *Federal Register* on September 26, 2017, announcing a public hearing on a potential approach for device sponsors who seek to obtain marketing authorization for their products that are intended for a new use with an approved, marketed drug when the sponsor for the approved, marketed drug does not wish to pursue or collaborate on the new use. In the document, in addition to seeking comments on the potential approach, FDA also welcomed comments on public health, scientific, regulatory, or legal considerations relating to other medical products intended for new uses with approved, marketed medical products of a different type where the sponsor for the approved, marketed product does not wish to pursue or collaborate on the new use. We are reopening the comment period in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the document published on September 26, 2017 (82 FR 44803). Submit either electronic or written comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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-5319 for "Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments." 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: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301-796-8930, combination@fda.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* on September 26, 2017 (82 FR 44803), FDA published a document announcing a public hearing on November 16, 2017, regarding a potential approach for device sponsors who seek to obtain marketing authorization for their products that are intended for a new use with an approved, marketed drug when the

sponsor for the approved, marketed drug does not wish to pursue or collaborate on the new use. The purpose of the public hearing was to obtain comments from stakeholders on the potential approach presented in the *Federal Register* document as well as comments on public health, scientific, regulatory, or legal considerations relating to other medical products intended for new uses with approved, marketed medical products of a different type where the sponsor for the approved, marketed product does not wish to pursue or collaborate on the new use. We sought this type of public engagement because of the potential importance of the issue for public health and the need for input across the medical product industry and among public health stakeholders regarding how FDA should proceed. The comments that FDA receives in relation to this public hearing may help inform the further development of this approach.

The document stated that comments would be accepted until January 15, 2018, and that untimely comments would not be considered. Near the end of the comment period, we received a request, submitted on behalf of several potential commenters, for more time to develop comments. We have considered this request and are reopening the comment period for an additional 30 days. We believe that this reopening allows adequate time for interested persons to submit comments without delaying further Agency efforts on this topic.

Dated: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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