4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA-2015-N-2002]

RIN 0910-AH19

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of comment period.

SUMMARY: In the Federal Register of January 9, 2017, the Food and Drug Administration (FDA or the Agency) issued a final rule entitled "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses' " (Final Rule). On March 20, 2017, FDA published a document in the Federal Register (Final Rule Extension) to delay the effective date of the Final Rule until March 19, 2018, and requested comments on particular issues raised in a petition for reconsideration and stay of action of the Final Rule. The petition for reconsideration raised questions about the amendments to the regulations regarding "intended uses" that are set forth in the Final Rule. In the Final Rule Extension FDA also requested comments regarding any aspect of the Final Rule, or with respect to issues relating to "intended uses" generally, and on whether the delay in the effective date should be modified or revoked. FDA is now issuing this document to extend the comment period. The Agency is 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 document delaying the effective date and seeking comment on the final rule published March 20, 2017 (82 FR 14319). Submit either electronic or written comments by July 18, 2017. For additional information on the comment date, see ADDRESSES and SUPPLEMENTARY INFORMATION.

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 July 18, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 18, 2017. 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): 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-2015-N-2002 for "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses'; Further Delayed Effective Date; Request for Comments; Extension of Comment Period." Received comments, those filed in a timely manner (see DATES), 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: 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert Berlin, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993, 301-796-8828.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 20, 2017, FDA published a document delaying the effective date of the January 9, 2017 (82 FR 2193), final rule entitled "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses' " until March 19, 2018, with a 60-day comment period. FDA requested comments on particular issues raised in a petition for reconsideration and stay of action of the Final Rule, as well as regarding any aspect of the Final Rule, or with respect to issues relating to "intended uses" generally. FDA also requested comments on whether the delay in the effective date of the Final Rule should be modified or revoked. Comments on these issues will inform FDA's thinking and next steps on these issues.

The Agency has received a request for a 30-day extension and another request for a 90-day extension of the comment period for the Final Rule Extension. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to issues FDA raised in the Final Rule Extension.

FDA has considered the requests and is extending the comment period for 60 days, until July 18, 2017. The Agency believes that a 60-day extension allows additional time for interested persons to submit comments on these important issues.

Dated: May 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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