DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1120

[Docket No. FDA–2013–N–0227]

Proposed Requirements for Tobacco Product Manufacturing Practice; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public oral hearing entitled ''Proposed Requirements for Tobacco Product Manufacturing Practice.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to prescribe current good manufacturing practice (cGMP) or hazard analysis and critical control point methodology (HACCP) regulations related to the manufacture, preproduction design validation, packing, and storage of tobacco products to protect public health and ensure compliance with the FD&C Act. In accordance with this provision, FDA is proposing requirements for tobacco product manufacturing practice (TPMP) elsewhere in this issue of the **Federal Register**. The FD&C Act further requires FDA to afford an opportunity for an oral hearing on the proposed regulation. We are holding this public oral hearing to carry out this statutory mandate and obtain information and views on the proposed TPMP requirements.

DATES: The public oral hearing will be held virtually on April 12, 2023, from 9:30 a.m. to 5 p.m. Eastern Time. All written notices of participation must be received by March 31, 2023 (email written notices of participation to: *CTPoutreach@fda.hhs.gov*). Either electronic or written comments on this public hearing must be submitted by September 6, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule published elsewhere in this issue of the **Federal Register** by September 6, 2023.

ADDRESSES: This public oral hearing will be held via an online teleconferencing platform. Additional details, such as the time of the public oral hearing and registration information, will be posted at *https://www.fda.gov/tobacco-products.* The online web conference meeting link can be accessed at *https://www.fda.gov/tobacco-products* on the day of the meeting.

All written notices of participation must be received by March 31, 2023 (email to: *CTPoutreach@fda.hhs.gov*). You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2013–N–0227 for ''Proposed Requirements for Tobacco Product Manufacturing Practices; Notice of 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Necola Staples or Robert Schwartz, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPOutreach@fda.hhs.gov* or *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA issued a proposed regulation on TPMP requirements (TPMP proposed rule). As described in the TPMP proposed rule, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) authorizes FDA to establish regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to cGMP or HACCP methodology. The TPMP proposed rule (proposed 21 CFR part 1120), if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products. These requirements, if finalized, will help protect the public health by ensuring that tobacco products are manufactured in facilities that meet basic requirements for manufacturing, packing, and storing tobacco products and are in compliance with chapter IX of the FD&C Act (21 U.S.C. 387 through 387u).

Section 906(e)(1)(B)(ii) of the FD&C Act requires FDA, before issuing a final TPMP regulation, to provide the public the opportunity for an oral hearing. To satisfy this requirement, FDA is holding this public oral hearing pursuant to part 15 (21 CFR part 15) to provide the opportunity for the public to present information and views on the proposed requirements.

II. Notice of Hearing Under Part 15

To satisfy the statutory requirement under section 906(e)(1)(B)(ii) of the FD&C Act, FDA will hold a public oral hearing consistent with part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA panelists, including subject matter experts from the Center for Tobacco Products. As provided in § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as provided in § 15.30(b) (see also *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

III. Topics for Discussion at the Public Oral Hearing

FDA is interested in the public's views, information, and any supporting data on the TPMP proposed rule, including the following topics:

- The proposed scope of the regulation to cover finished and bulk tobacco product manufacturers, including specification developers.
- Potential changes to the scope of the regulation, such as expanding the scope to cover manufacturers of all regulated tobacco products, including all components or parts, or limiting the scope to cover only manufacturers of certain products.
- FDA's proposed ''umbrella'' approach with flexible requirements to all affected entities as opposed to applying only specific or additional requirements for certain types of tobacco products.
- Product specifications in the Master Manufacturing Record (MMR). The proposed approach for the MMR would include any requirement established by the manufacturer as well as, at a minimum, certain specifications related to product content, design, and any applicable product standards.
- Design and development activities needed to control the risks associated with finished and bulk tobacco product and its production processes, packing, and storage. The proposed risk management process would include the risk treatment requirements intended to help prevent the manufacture and distribution of nonconforming and/or contaminated tobacco product.
- The proposed effective date—2 years for manufacturers (other than small tobacco product manufacturers) and a total of 6 years for small tobacco product manufacturers—for complying with any TPMP regulations.

IV. Participating in the Public Oral Hearing

Registration: To register to attend the free public oral hearing, please visit the following website: *https://www.fda.gov/tobacco-products.* Registration information will be posted soon. Live closed captioning will be provided during the public oral hearing. Additional information on requests for special accommodations due to a disability will be provided during registration.

Written Notice of Participation: During online registration you may indicate if you wish to present information and views at the hearing (oral statements without slides). FDA will do its best to accommodate requests to make public presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants ahead of the hearing. All written notices of participation must be received by March 31, 2023, 11:59 p.m. Eastern Time (email to: *CTPoutreach@fda.hhs.gov*). No commercial or promotional material will be permitted to be presented or distributed at the public oral hearing.

Transcripts: Please be advised that as soon as a transcript of the public oral hearing is available, it will be accessible at *https://www.regulations.gov.* Once available, the transcript may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/tobacco-products.*

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04592 Filed 3–8–23; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 13

[NPS–AKRO–35327; PPAKAKROZ5, PPMPRLE1Y.L00000]

RIN 1024–AE70

Alaska; Hunting and Trapping in National Preserves—Extension of Public Comment Period

AGENCY: National Park Service, Interior.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The National Park Service extends the public comment period for a proposed rule that would amend regulations for sport hunting and trapping in national preserves in Alaska.