Dated: October 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4188]

Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies.'' The draft guidance provides information intended to assist applicants design and conduct tobacco product perception and intention (TPPI) studies that may be submitted as part of a modified risk tobacco product application (MRTPA), a premarket tobacco product application (PMTA), or a substantial equivalence (SE) report. The draft guidance is intended to discuss a variety of scientific issues applicants may want to consider as they design and conduct TPPI studies.

DATES: Submit either electronic or written comments on the draft guidance by December 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments as follows:

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–2019–D–4188 for ''Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies; Draft Guidance for Industry; Availability.'' Received comments 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 office 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability for public comment of a draft guidance for industry entitled ''Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies.''

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires new tobacco products to undergo review and receive an order from FDA before being

introduced or delivered for introduction into interstate commerce. The FD&C Act establishes three pathways to market for new tobacco products:

- Submission of a PMTA under section 910(b) of the FD&C Act (21 U.S.C. 387j(b)) and receipt of a marketing order under section 910(c)(1)(A)(i),
- Submission of a SE report under section 905(j)(1)(A) (21 U.S.C. 387e(j)(1)(A)) and receipt of an SE marketing order, or
- Submission of a request for an exemption from the requirements of demonstrating SE under section 905(j)(3) and receipt of an exemption from FDA (implemented at § 1107.1 (21 CFR 1107.1)).

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

The draft guidance is intended to assist applicants design and conduct TPPI studies that may be submitted as part of an MRTPA, a PMTA, or a SE report. Conducting TPPI studies can assist applicants submitting tobacco product applications demonstrate that their product meets applicable requirements to receive marketing authorization under the appropriate pathway. For example, TPPI studies can be used to assess, among other things, individuals' perceptions of tobacco products, understanding of tobacco product information, and intention to use tobacco products. The draft guidance is intended to address a variety of scientific issues applicants may consider as they design and conduct TPPI studies to support tobacco product applications.

II. Significance of Draft Guidance

FDA is issuing this draft guidance 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 designing and conducting tobacco product perception and intention studies. 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. 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 § 1107.1(b) and (c) have been approved under OMB control number 0910–0684. The collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910–0768. The collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either *https://www.regulations.gov* or *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance.*

Dated: October 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1862]

The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following virtual public meeting entitled ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security.'' The purpose of the public meeting is to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA and provide input on strategies and issues related to the enhanced drug distribution security provisions of the Drug Supply Chain Security Act (DSCSA) and the results of FDA's DSCSA Pilot Project Program.

DATES: The public meeting will be held on December 8 and 9, 2020, from 9 a.m. to 4 p.m., Eastern Time, each day, and will take place virtually (by webcast only). Submit either electronic or written comments on this public meeting by December 28, 2020.

ADDRESSES: The public meeting will be held virtually and hosted by FDA. Registration to participate in this meeting and other information can be found at *https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security.* See the **SUPPLEMENTARY INFORMATION** section for registration date and other information.

Comments: To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic and written comments must be submitted on or before December 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2020. 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'').