TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Indepth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Indepth Interviews, Cognitive Interviews	9	1	9	1	9
Indepth Interviews Screener	900	1	900	0.083 (5 minutes)	75
Indepth Interviews	180	1	180	1	180
Survey Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Survey Cognitive Interviews	9	1	9	1	9
Pretest Survey Screener	750	1	750	0.083 (5 minutes)	62
Pretest Survey	150	1	150	0.25 (15 minutes)	38
Self-Administered Surveys—Study Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys	15,000	1	15,000	0.25 (15 minutes)	3,750
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes)	15
Focus Group/Small Group, Cognitive Groups	60	1	60	1.5 (90 minutes)	90
Focus Group/Small Group Participant Screening	720	1	720	0.083 (5 minutes)	60
Focus Group/Small Group Discussion	240	1	240	1.5 (90 minutes)	360
Total					10,881

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18265 Filed 8–23–22; 8:45 am]

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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; 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 final guidance for industry entitled ''Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies.'' The final 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 final guidance discusses a variety of scientific issues applicants may want to consider as they design and conduct TPPI studies.

DATES: The announcement of the guidance is published in the **Federal Register** on August 24, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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; 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 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 guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, 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 guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted 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 FD&C Act, as amended by the Tobacco Control Act, requires new tobacco products to undergo premarket 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) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)),
- Submission of a SE report under section 905(j)(1)(A) of the FD&C Act (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) of the FD&C Act (21 U.S.C. 387e(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 final 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. TPPI studies can help applicants demonstrate that their product meets the applicable premarket authorization standard. For example, TPPI studies can be used to assess, among other things, individuals' perceptions of tobacco products, understanding of tobacco product information, and intentions to use tobacco products. The final 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.

A notice of availability for the draft guidance appeared in the **Federal Register** of October 28, 2020 (85 FR 68341). FDA considered comments received and revised the final guidance as appropriate in response to the comments. This included, for example, reorganizing the structure of the guidance to ensure the document is more user-friendly, defining additional terms to improve clarity, and providing additional information on various recommendations related to the development of TPPI studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on designing and conducting tobacco product perception and intention studies, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. This guidance provides non-binding recommendations on TPPI studies and does not establish requirements for submitting studies in support of an application. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 under 21 CFR part 1114 have been approved under OMB control number 0910–0879. The collections of information in 21 CFR part 1107, subparts B through E, have been approved under OMB control number 0910–0673.

III. Electronic Access

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

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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