TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	62	1	62	2	124

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

TABLE 3.—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a)	22	1	22	1	22

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

Our estimated burden for the information collection reflects an increase of 360 total burden hours and a corresponding increase of five total annual responses. For efficiency of Agency operations, we are consolidating the related information activity and account for burden associated with HDE regulations currently approved in OMB control number 0910–0661. As a result, there is an increase in the total number of burden hours for this information collection.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18271 Filed 8–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0430]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 23, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0876. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control Number 0910–0876—Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role consumers and stakeholders play in ensuring the safety of the food supply, which helps ensure that suppliers produce food that meets U.S. safety standards.

Occasionally, FDA will need to communicate with consumers and other stakeholders about immediate health issues that could affect public health and safety. This collection of information allows the use of fast-track methods of communication such as quick turnaround surveys, focus groups, and indepth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health significance. We plan on using these methods of communication to collect vital public health and safety information.

For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information provided by this collection of information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers of FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation will be voluntary.

In the **Federal Register** of April 18, 2022 (87 FR 22906), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, they were not responsive to the four collection of information topics solicited.

We estimate the burden of this collection of information as follows:

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]

BILLING CODE 4164–01–P

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