VI. Duration of the OCT 510(k) Pilot Program

FDA intends to accept requests for participation in the voluntary OCT 510(k) Pilot Program from the date of publication in the **Federal Register** through one year, or until the time when a total of nine participants have been enrolled.

VII. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations and guidance. 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 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120. The collections of information in ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

VIII. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. MDUFA IV Commitment Letter, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*
2. FDA Guidance for Industry and FDA Staff ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' dated September 29, 2017, available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.*
3. FDA Guidance for Industry and FDA Staff ''Refuse to Accept Policy for 510(k)s'' dated January 30, 2018, available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.*
4. FDA Guidance for Industry and FDA Staff ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' dated July 28, 2014, available at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.*

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23059 Filed 10–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1533]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Panel of Tobacco Consumer Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the National Panel of Tobacco Consumer Studies.

DATES: Submit either electronic or written comments on the collection of information by December 24, 2018.

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 December 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2018. 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):* 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–2014–N–1533 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; National Panel of Tobacco Consumer Studies.'' 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.

- *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.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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

National Panel of Tobacco Consumer Studies

OMB Control Number 0910–0815—Extension

I. Background

FDA's Center for Tobacco Products (CTP) established a national, primarily web-based panel of about 4,000 tobacco users. The panel includes individuals who can participate in up to eight studies over a 3-year period to assess consumers' responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products. CTP established the panel of consumers because currently existing panels have a number of significant limitations. First, many existing consumer panels are drawn from convenience samples that limit the generalizability of study findings (Ref. 1). Second, although at least two probability-based panels of consumers exist in the United States, there is a concern that responses to the studies using tobacco users in these panels may be biased due to panel conditioning effects (Refs. 2 and 3). That is, consumers in these panels complete surveys so frequently that their responses may not adequately represent the population as a whole. Panel conditioning has been associated with repeated measurement on the same topic (Ref. 4), panel tenure (Ref. 2), and frequency of the survey request (Ref. 3). This issue is of particular concern for tobacco users who represent a minority of the members in the panels, and so may be more likely to be selected for participation in experiments and/or surveys related to tobacco products. Third, a key benefit of the web panel approach is that the surveys can include multimedia, such as images of tobacco product packages, tobacco advertising, new and existing warning statements and labels, and potential reduced harm claims in the form of labels and print advertisements. Establishing a primarily web-based panel of tobacco users through in-person probability-based recruitment of eligible adults and limiting the number of times individuals participate in tobacco-related studies will result in nationally representative and unbiased data collection on matters of importance for FDA.

With this submission, FDA seeks an extension on the currently approved information collection request from OMB for remaining planned panel maintenance and replenishment activities for the National Panel of Tobacco Consumer Studies. Data collection activities will involve mail and in-person household screening, in-person recruitment of tobacco users, enrollment of selected household members, and administration of a baseline survey, following all required informed consent procedures for panel members. Panel members will be asked to participate in up to eight experimental and observational studies over the 3-year panel commitment period. The first of these panel studies, Study A ''Brands and Purchasing Behavior,'' was included in the currently approved information collection request; approval for Studies B, C, and D are included in this extension request. The first of these panel studies, Study A ''Brands and Purchasing Behavior,'' was included in the currently approved information collection request. Study B ''Coupons and Free Samples,'' Study C ''Consumer Perceptions of Product Standards,'' and Study D ''Hypothetical Purchasing of Tobacco Products'' are included in this request for extension. Study B will be an observational study offered to all panelists that will provide a more in-depth examination of tobacco product promotions, namely free samples and coupons, after the ban on distribution of free samples of tobacco products (with the exception of certain smokeless tobacco exemptions) that went into effect when FDA finalized the ''Deeming Rule'' on August 8, 2016 (published May 10, 2016 (81 FR 28973)) that extended FDA's regulatory authority to all tobacco products. Study C will be an experimental study examining how a hypothetical tobacco product standard may impact consumers' perceptions, attitudes, and tobacco use behavioral intentions. Study D will be an experimental study using behavioral economic methods that seeks to understand how the availability or lack of availability of menthol cigarettes potentially impacts adult cigarette smokers' product purchasing choices. The current request also seeks approval to update the estimated burden for an additional year of panel replenishment. The overall purpose of the data collection is to collect information from

a national sample of tobacco users to provide data that may be used to develop and support FDA's policies related to tobacco products, including their labels, labeling, and advertising.

The target population for the panel is tobacco users aged 18 years and older in housing units and in noninstitutionalized group quarters in the 50 states and the District of Columbia. A stratified four-stage sample design was used, with a goal of recruiting 4,000 adult tobacco users into the sample panel. The sample is designed to allow in-depth analysis of subgroups of interest and to the extent possible, provide insight into tobacco users more generally. Replenishment will be conducted to maintain the panel with a constant number of members following existing panel recruitment and enrollment methods.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/respondent	No. of respondents	No. of responses per respondent [2]	Total annual responses [3]	Average burden per response	Total hours [3]
Household Screening Respondent [4]	35,885	0.33	11,842	0.13 (8 minutes)	1,539
Panel Member Enrollment Survey	4,000	0.33	1,320	0.25 (15 minutes)	330
Panel Member Baseline Survey		0.33	1,320	0.25 (15 minutes)	330
Study A		0.33	1,320	0.33 (20 minutes)	436
Study B		0.33	1,320	0.33 (20 minutes)	436
Study C		0.33	1,320	0.33 (20 minutes)	436
Study D		0.33	1,320	0.33 (20 minutes)	436
Panel Replenishment Household Screening Respondent.	30,855	0.33	10,182	0.13 (8 minutes)	1,324
Panel Replenishment Enrollment Survey [5].	4,200	0.33	1,386	0.25 (15 minutes)	347
Panel Replenishment Baseline Survey [5]		0.33	1,386	0.25 (15 minutes)	347
Total					5,961

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Assumes respondents will participate once over a 3-year period, or 0.33 responses annually.
[3] Amounts are rounded to the nearest whole number.
[4] Includes both mail and field screening.
[5] Assumes 1,400 additional panel members will be recruited annually (4,200 total) as part of the panel replenishment effort.

FDA's burden estimate is based on timed-readings of each instrument, including the mail and field screeners, enrollment survey, baseline survey, and Study A–D questionnaires. Of the total screening respondents, we expect 25 percent will respond only in the mail screening (household deemed ineligible), 65 percent will respond only in the field screening (mail screening nonrespondents), and the remaining 10 percent will respond in both the mail screening and the field screening. The latter includes eligible households from the mail screening that are subsequently field-screened to sample the panel member, and the 10 percent quality control sample of households whose mail screening ineligibility is verified through in-person screening. This assumes an estimated 10,285 household screening respondent during yearly panel replenishment (30,855 total). Replenishment panel members replace original panel members and become part of the 4,000-member panel that receives experimental/observational and panel maintenance surveys. This extension reflects an increase of 1,527 hours due to an additional year of panel replenishment and fielding of Studies B, C, and D. The estimated burden assumes 10,285 household screening respondents during yearly panel replenishment (30,855 total) and 1,400 additional panel members recruited annually (4,200 total) as part of the panel replenishment effort.

II. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Baker, R., Blumberg, S., Brick, M., et al., 2010, ''American Association for Public Opinion Research Report on Online Panels.'' *Public Opinion Quarterly,* 74(4), pp. 711–781.
2. Coen, T., Lorch, J. and Piekarski, L., 2005, ''The Effects of Survey Frequency on Panelists' Responses. Worldwide Panel Research: Developments and Progress,'' Amsterdam, European Society for Opinion and Marketing Research.
3. Nancarrow, C. and Catwright, T., 2007, ''Online Access Panels and Tracking Research, The Conditioning Issue,'' *International Journal of Market Research,* 49(5), pp. 435–447.
4. Kruse, Y., Callegaro, M., Dennis, J. M., et al., 2009, Panel Conditioning and Attrition in the AP-Yahoo! News Election Panel Study, Paper presented at the American Association for Public Opinion Research 64th Annual Conference.

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23060 Filed 10–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Children's Graduate Medical Education Quality Bonus System (QBS) Initiative Response Form, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection