

2016, including experimental products and developmental products intended for introduction into the market for consumer use. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands “current or future tobacco products” to refer to products commercially distributed on or after June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

All manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and

December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28974 at 29008–09). Additionally, FDA extended the compliance deadlines by an additional 6 months to May 8, 2018, for small-scale manufacturers in the areas impacted by recent natural disasters. Thereafter, FDA’s compliance plan requests deemed manufacturers provide tobacco health document submissions from the specified period at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

In the **Federal Register** of August 23, 2018 (83 FR 42664), FDA published a 60-day notice requesting public

comment on the proposed collection of information. One comment was received that was PRA related.

(Comment) FDA received one comment requesting that FDA exercise enforcement discretion by suspending the collection and utilizing the Agency’s other authorities to inform regulatory decisions due to the associated burden of manufacturers to retain documents for future submission to FDA. Additionally, the commenter requests FDA to narrow the scope of the collection by defining key terms.

(Response) At this time, FDA does not intend to suspend the collection as respondents have the option to submit documents directly to FDA independent of the compliance policy. Additionally, at this time, FDA believes narrowly defining health effects could potentially exclude relevant scientific information from being retained by industry and subsequently submitted as part of future health document submissions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743 .....	10	3.2	32	50	1,600

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other tobacco products as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few

manufacturers or importers of deemed tobacco products, or agents thereof, would have health documents to submit. In addition to the existing 4 respondents, the Agency estimates that approximately 6 submissions (2 for cigar manufacturers, 1 for pipe and waterpipe tobacco manufacturers, 1 for other tobacco product manufacturers, 1 for tobacco importers, and 1 for importers of ENDS that are considered manufacturers) will be submitted on an annual basis for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

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

Dated: May 14, 2019.  
**Lowell J. Schiller**,  
*Principal Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1533]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Panel of Tobacco Consumer Studies**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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:** Fax written comments on the collection of information by June 19, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0815. 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](mailto: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.

**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 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.

In the **Federal Register** of October 23, 2018 (83 FR 53485), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 10 comments; however, only 1 was PRA related.

(Comment) One commenter supports FDA's establishment of a tobacco user panel, adding that high-quality research is critical to successful implementation of many provisions of tobacco policy. The commenter further stated that the research panel can provide FDA with critical information on how adult tobacco users respond to tobacco marketing, product labels, warning statements, and other communications about tobacco products. The commenter also noted the ability to have its own panel of tobacco users will allow FDA to gather more reliable information in a more efficient manner.

(Response) FDA agrees with this comment and believes the panel will be a valuable tool for conducting new observational and experimental studies.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity/respondent	Number of respondents	Number of responses per respondent <sup>2</sup>	Total annual responses <sup>3</sup>	Average burden per response	Total hours <sup>3</sup>
Household Screening Respondent .....	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 <sup>4</sup> .....	33,355	0.33	11,007	0.13 (8 minutes) .....	1,431
Panel Replenishment Enrollment Survey <sup>4</sup> .....	4,600	0.33	1,518	0.25 (15 minutes) .....	380
Panel Replenishment Baseline Survey <sup>4</sup> .....		0.33	1,518	0.25 (15 minutes) .....	380
<b>Total</b> .....					<b>6,134</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Assumes respondents will participate once over a 3-year period, or 0.33 responses annually.

<sup>3</sup> Amounts are rounded to the nearest whole number.

<sup>4</sup> Assumes an estimated 10,285 mail and field household screening respondents during yearly panel replenishment and 1,400 additional panel members will be recruited annually as part of the panel replenishment effort, as well as an additional 2,500 household screening respondents during replenishment and an additional 400 panel replenishment enrollment and baseline survey respondents should annual attrition rates be higher than expected.

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 through 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. The estimated burden published in the 60-day notice assumed an estimated 10,285 household screening respondent during yearly panel replenishment (30,855 total) and 1,400 additional panel members recruited annually (4,200 total). In this notice, we included 2,500 additional household screening respondents during replenishment, and an additional 400 panel replenishment enrollment and baseline survey respondents as part of the panel replenishment effort (should annual attrition rates be higher than expected). The new total is 33,355 household screening respondents and a total of 4,600 panel members recruited. Replenishment panel members replace original panel members and become part of the 4,000-member panel that receives experimental/observational and panel maintenance surveys. Overall, this extension reflects an increase of

1,700 hours due to an additional year of panel replenishment and fielding of studies B, C, and D.

**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; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. 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 Cartwright, 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: May 14, 2019.

**Lowell J. Schiller**,  
Principal Associate Commissioner for Policy.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier OS–4040–0002]

**Agency Information Collection Request. 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.  
**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 19, 2019.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Ed Calimag, [ed.calimag@hhs.gov](mailto:ed.calimag@hhs.gov) or (202) 690–7569. When submitting comments or requesting information, please include the document identifier 4040–0002–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information