regulations and ORR policies and procedures.

Melody Wayland,

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[FR Doc. 2014–24555 Filed 10–15–14; 8:45 am]

BILLING CODE 4184–45–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; Establishment of a Tobacco User Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the establishment of a probability-based panel of tobacco users.

DATES: Submit either electronic or written comments on the collection of information by December 15, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 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.

Establishment of a Tobacco User Panel—(OMB Control Number 0910–NEW)

The Food and Drug Administration's Center for Tobacco Products (CTP) proposes to establish a high quality, probability-based, primarily Web-based panel of 4,000 tobacco users. The panel will include individuals who can participate in up to 8 studies over a 3-year period to assess consumers' responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products. CTP proposed the establishment of the panel of consumers because currently existing Web-based panels have a number of significant limitations. First, most existing consumer panels are drawn from convenience samples that limit the generalizability of study findings (Baker et al., 2010). 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 (e.g., Coen, Lorch and Piekarski, 2005; Nancarrow and Catwright, 2007). 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 (e.g., Kruse et al., 2009), panel tenure (e.g., Coen, Lorch and Piekarski, 2005), and frequency of the survey request (e.g., Nancarrow and Catwright, 2007). 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, the FDA seeks approval from OMB to establish the Tobacco User Panel, a nationally representative, primarily web-based panel of 4,000 current tobacco users. Data collection activities will involve pilot testing of panel recruitment and management procedures and systems, mail and in-person household screening, in-person recruitment of tobacco users, enrollment of selected household members, administration of a baseline survey, and panel maintenance surveys, following all required informed consent procedures for panel members. Once the panel is established, 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 studies (Study 1) is included in this information collection request; approval for the remainder of the studies will be appear in future requests. The current request also seeks approval to conduct up to two rounds of cognitive testing of new survey items and up to two focus groups to further refine study protocols, as needed. With this clearance, study investigators will be able to use the OMB approved data collection methods where appropriate to plan and implement the national panel.

The overall purpose of the proposed data collection is to collect information from a representative 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. Data will be collected from the panel primarily through the use of randomized experimental designs, however, there may be data collected through the use of other methods, such as surveys, interviews, or online group discussions. Given the limitations on the existing Web-based panels, it is important to develop a new panel of tobacco users that balances the need to conduct experiments while limiting the number of tobacco-related studies per year so as to not bias study results.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity or type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Household Screening Respondent	29,385	0.33	9,697	0.16 (10 minutes)	1,552
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
Panel Maintenance/Bi-annual Update Surveys		3.0	12,000	0.08 (5 minutes)	960
Experimental/Observational Studies *		2.7	10,800	0.33 (20 minutes)	3,564
Panel Replenishment Screening Respondent	10,285	0.50	5,143	0.16 (10 minutes)	823
Panel Replenishment Enrollment Survey **	2,800	0.33	924	0.25 (15 minutes)	231
Panel Replenishment Baseline Survey **	2,800	0.33	924	0.25 (15 minutes)	231
Cognitive Interview Subjects	20	0.33	7	1.0	7
Focus Group Subjects	20	0.33	7	1.5	10
Total	49,310				8,038

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

* Includes a total of 8 experimental or observational studies over a 3-year period for each of the 4,000 panel members who are active at the time of each study. The first study (Study 1) is included in this clearance request; the remaining studies will be funded under separate task orders but are included in this table to present an overall estimate of the burden for each participating panel member.

** Assumes 1,400 additional panel members will be recruited annually (2,800 total) as part of the panel replenishment effort.

The burden above was estimated using data from timed-readings of each instrument, including the mail and field screeners, enrollment survey, baseline survey, panel maintenance questionnaires, and Study 1 questionnaire.

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24538 Filed 10–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0555]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

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: Fax written comments on the collection of information by November 17, 2014.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0442. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Medical Devices; Device Tracking—21 CFR part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''), or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and