

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
201.25(d)	2	1	2	24	48

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

Dated: August 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20205 Filed 8–16–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0876]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pretesting of Tobacco Communications

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, 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 pretesting of tobacco communications.

DATES: Submit either electronic or written comments on the collection of information by October 16, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–

400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@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.

Pretesting of Tobacco Communications—(OMB Control Number 0910–0674)—Extension

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) and to develop stronger health warnings on tobacco packaging

as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for FDA to conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C. 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences. The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target audiences. FDA must first understand critical influences on people’s decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. Knowledge of these decisionmaking processes will be applied by FDA to help design effective communication strategies, messages, and warning labels. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience—its attitudes, beliefs, and behaviors—and use risk communications; (2) more efficiently and effectively design messages and select formats that have the greatest potential to influence the target audience’s attitudes and behavior in a favorable way; (3) determine the best promotion and distribution channels to reach the target audience with appropriate messages; and (4) expend limited program resource dollars wisely and effectively.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews	144	1	144	1.5 hours	216
Intercept Interviews: Central Location	600	1	600	0.25 (15 minutes)	150
Intercept Interviews: Telephone	² 10,000	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,304	2,644
Physician Focus Group Interviews	144	1	144	1.5 hours	216
Total (Physician)	144	216
Total (Overall)	16,448	2,860

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

² Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1-800 number.

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for illustrative purposes, table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the 3-year period. Time to read, view, or listen to the message being tested is built into the “Hours per Response” figures.

Dated: August 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20206 Filed 8-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 21, 2012.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Report to the Director, NIDCR.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, 10, Bethesda, MD 20892.

Closed: 1:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, 10, Bethesda, MD 20892.

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 13, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-20275 Filed 8-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cures Acceleration Network Review Board.

Date: September 14, 2012.

Time: 8:30 a.m. to 2:30 p.m.

Agenda: Report from the Acting Institute Director.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Jane A. Steinberg, Ph.D., Executive Secretary, National Center for