

be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**Contact Person:** Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [ACRHD@fda.hhs.gov](mailto:ACRHD@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** On March 5, 2013, the committees will discuss whether the benefit of calcitonin salmon for the treatment of postmenopausal osteoporosis (thinning and weakening of bones that increase the chance of having a broken bone) outweighs a potential risk of cancer. Calcitonin salmon products approved for the treatment of osteoporosis include: Miacalcin (calcitonin salmon) injection and nasal spray, submitted by Novartis Pharmaceuticals Corporation; Fortical (calcitonin salmon recombinant) nasal spray, submitted by Upsher Smith Laboratories; and the generic equivalents of these products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 15, 2013.

Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 7, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 8, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 8, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-00507 Filed 1-11-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request (60-Day FRN): The National Cancer Institute (NCI) SmokefreeTXT (Text Message) Program Evaluation (NCI)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To submit comments in writing, request more information on the proposed project, or to obtain a copy of the data collection plans and instruments, contact: Erik Augustson, Ph.D., MPH, Behavioral Scientist/Health Science Administrator, Division of Cancer Control and Population Sciences, 6130 Executive Blvd., EPN-4034, Bethesda, MD 20892-7337 or call non-toll-free number 301-435-7610 or Email your request, including your address to: [augustse@mail.nih.gov](mailto:augustse@mail.nih.gov).

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**Proposed Collection:** The National Cancer Institute (NCI) SmokefreeTXT Program Evaluation (NCI), 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

#### **Need and Use of Information**

**Collection:** This is a request for OMB to approve the new submission titled, "The National Cancer Institute (NCI) SmokefreeTXT Program Evaluation" for 3 years. The supporting statements and various attachments accompany this memorandum.

This study seeks to assess the efficacy of the SmokefreeTXT program, a text message smoking cessation intervention designed for young adult smokers ages 18-29. The SmokefreeTXT program is a component of a larger series of eHealth/mHealth tobacco cessation intervention programs. SmokefreeTXT has been developed (and is managed) by the

National Cancer Institute (NCI) Tobacco Control Research Branch (TCRB) at the request of the Office of the Assistant Secretary for Health (OASH) at the Department of Health and Human Services (DHHS).

The study seeks to recruit a large sample of young adult smokers ages 18–29 to examine how exposure to the SmokefreeTXT intervention affects participants' success at quitting smoking. There will be 3-arms to the study; participants will be enrolled for

a maximum of 8 weeks of treatment in the SmokefreeTXT program, with frequency and duration of the treatment varying by study arm. The SmokefreeTXT Study will collect self-reported cessation data using the bidirectional aspect of text-messaging service and a series of web-based surveys. All web-based survey data will be collected and stored by a third-party, Research Triangle Institute International (RTI). Respondents will complete the following 5 web-based surveys for a

total of 7,136 burden hours: (1) Pre-treatment baseline survey; (2) one week post quit date questionnaire; (3) end of active cessation treatment questionnaire; (4) 12-week post-treatment questionnaire; (5) 24-weeks post-treatment questionnaire.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 8,353.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total burden hours
Young Adults .....	Screener/recruitment .....	21,000	1	5/60	1,750
	Baseline .....	4,248	1	30/60	2,124
	1 week post-quit date .....	3,399	1	15/60	850
	6 weeks post quit date .....	2,721	1	30/60	1,361
	12 weeks post-treatment .....	2,178	1	15/60	545
	24 weeks post treatment .....	1,308	1	15/60	327
	Exit Survey/Script .....	16,752	1	5/60	1,396
	Total .....	.....	.....	.....	8,353

Dated: January 8, 2013.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, NCI, NIH.*

[FR Doc. 2013–00572 Filed 1–11–13; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

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:* Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section

*Date:* February 6, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton DFW Airport, 4440 W. John Carpenter Frwy., Irving, TX 75063.

*Contact Person:* Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, [zhengli@csr.nih.gov](mailto:zhengli@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR: Selected Topics in Transfusion Medicine.

*Date:* February 6–7, 2013.

*Time:* 11:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, [shahb@csr.nih.gov](mailto:shahb@csr.nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

*Date:* February 7–8, 2013.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

*Contact Person:* Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, (301) 594–1245, [ivinsj@csr.nih.gov](mailto:ivinsj@csr.nih.gov).

*Name of Committee:* Oncology 1-Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

*Date:* February 11–12, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

*Contact Person:* Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, [sizemoren@csr.nih.gov](mailto:sizemoren@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Hepatobiliary Pathophysiology Study Section.

*Date:* February 11–12, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Bonnie L. Burgess-Beusse, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–435–1783, [beusseb@mail.nih.gov](mailto:beusseb@mail.nih.gov).

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.

*Date:* February 11–12, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of