Dated: April 14, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8977 Filed 4–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI); Correction Notice

The **Federal Register** notice published on March 3, 2010 (75 FR 9902) announcing the proposed collection and comment request for the project titled, "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)" was submitted with errors. The burden table did not take into account the time related to complete the Phase III CATI as well as several telephone calls to schedule appointments and to follow up with instructions regarding the biospecimens collection. The corrected annual reporting burden is as follows:

TABLE A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent	Instrument	Estimated annual number of respondents	Frequency of response	Average time per response minutes/hour	Annual burden hours
Private Applicators, Spouses, Commercial Applicators.	Phase III Telephone Interview & Buccal Cell Scripts.	150	1	5/60 (0.083)	12.50
Private Applicators, Spouses, Commercial Applicators.	Phase III CATI	150	1	35/60 (0.583)	87.50
Private Applicators, Spouses, Commercial Applicators.	Phase III Buccal Cell Reminder, Missing or Damaged Scripts.	150	1	5/60 (0.083)	12.50
Private Applicators	BEEA CATI Screener	960	1	20/60 (0.33)	320.00
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 1.	310	1	20/60 (0.33)	5.17
Private Applicators	BEEA Schedule Home Visit Script.	10	3	5/60 (0.33)	2.50
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 3.	10	3	≤ 20/60 (0.33)	10.00
Total		1740			450.17

Dated: April 14, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–9098 Filed 4–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0600]

Guidance for Industry on Tobacco Health Document Submission; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Tobacco Health Document Submission." The guidance document is intended to assist persons making certain document submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Tobacco Health Document Submission" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *Beth.Buckler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 28, 2009 (74 FR 68629), FDA announced the availability of a draft guidance entitled "Tobacco Health Document Submission." The agency considered received comments as it finalized this guidance. The guidance document is intended to assist persons making certain document submissions to FDA under the Tobacco Control Act (Public Law 111–31).

The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 904(a)(4) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological,

behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and accessibility of submitted documents. Therefore, FDA does not intend to enforce the December 22, 2009, deadline provided you submit by April 30, 2010, all documents described in section 904(a)(4) of the act developed between June 22, 2009 and December 31, 2009.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on "Tobacco Health Document Submission." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection(s) of information in this guidance was approved under OMB control number 0910–0654.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: April 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9134 Filed 4–16–10; 11:15 am]

BILLING CODE 4160–01–S

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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Sensory.

Date: May 4–5, 2010.

Time: 7 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bernard F. Driscoll, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, (301) 435–1242, *driscolb@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–BST Consolidated: Member Conflict.

Date: May 6, 2010.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–408–9971, *fanp@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Bioengineering Sciences and Technologies.

Date: May 7, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–408–9971, *fanp@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Clinical and Health Services Research.

Date: May 18, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Sand Key Resort, 1160 Gulf Boulevard, Clearwater Beach, FL 33767.

Contact Person: Jacinta Bronte-Tinkew, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 435–1503, *brontetinkewjm@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.

Date: May 24–25, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 1960–A Chain Bridge Road, Mclean, VA 22102.

Contact Person: Martha Faraday, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, 301–435–3575, *faradaym@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Learning and Memory Study Section.

Date: May 26, 2010.

Time: 8:30 .a.m to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Bernard F. Driscoll, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, (301) 435–1242, *driscolb@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

Date: May 27–28, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 1250 22nd Street, NW., Washington, DC 20037.