

FDA announced the availability of a guidance on this collection in the **Federal Register** of April 20, 2010 (75 FR 20606), and requested tobacco health documents that were created during the period from June 23, 2009, through December 31, 2009. The guidance stated that information required under section 904(a)(4) must be submitted to FDA beginning December 22, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the specified period for any manufacturers, importers, or their agents who still have documents to submit.

FDA has been collecting the information submitted pursuant to section 904(a)(4) through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. In both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification: Submitter type, company name, address, country, company headquarters Dun and Bradstreet number, and company headquarters Facility Establishment Identifier number;
- Submitter point of contact: Contact name, title, position title, email, telephone, and fax; and

- Submission format and contents (as applicable):
 - Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software;
 - Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes; and
 - Whether or not a submission is being provided.
- Confirmation statement (with identification and signature of submitter including name, company name, address, position title, email, telephone, and fax); and
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
 - Health, behavioral, toxicological, or physiological effects;
 - Specific current or future tobacco product(s);
 - Class of current or future tobacco product(s);
 - Specific ingredient(s), constituent(s), component(s), or additive(s);
 - Class of ingredient(s), constituent(s), component(s), or additive(s).
- Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (e.g., code) names; special instructions for loading or compiling submission; and
- Document metadata: Date document was created, document author(s),

document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, and Bates number ranges for documents attached to a submitted email.

In addition to the electronic and paper forms, the guidance that FDA issued in April 2010 (75 FR 20606) was intended to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a Web tutorial on the electronic portal.

The estimated 50 hours per response burden is based on the average burden estimate among all 4 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. The number of documents received each year since the original collection period has fallen to less than 5 percent of the number received in the original collection period. FDA expects this is because documents created within the specified period have already been submitted. Also, the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be at most, 5 percent of the original burden.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 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 | 4 | 2 | 8 | 50 | 400 |

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

Dated: April 4, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will

submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email paperwork@hrsa.gov or call the HRSA Reports Clearance Office at (301) 443-1984.

Information Collection Request Title: Corps Community Day Event Form (OMB No. 0915-xxxx)—[NEW]

Abstract: Corps Community Day was created in 2011 and celebrates the

National Health Service Corps (NHSC) every October during National Primary Care Week. The NHSC is a program administered by the Bureau of Clinician Recruitment and Service (BCRS) within HRSA. The goals of Corps Community Day encompass the following: increase awareness of the NHSC to potential applicants and the greater primary health community; create a sense of community and connectedness among NHSC program participants, alumni, partners, and staff; and underscore the NHSC's role in bringing primary health care services to the nation's neediest communities. Current program participants, alumni, NHSC Ambassadors, sites, primary care organizations, and professional associations plan events and report the details of their events to BCRS so that

they can be added to the state-by-state map of events. In order to avoid duplication of effort, eliminate confusion regarding allowable event dates, avoid data entry errors, and implement a brief post-event satisfaction survey, BCRS would like to implement a standard form that event planners will use to report to BCRS. The fillable form will be available online and will have less than 20 fields for event planners to populate to submit for inclusion on the map. There will also be approximately 5 fields to populate following the event to measure satisfaction. Both the pre-event and post-event data fields will be held in one form.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain,

disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The annual estimate of burden is as follows:

| Form name | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|-----------------------|--------------------------|-----------------|--------------------|--------------------|
| Corps Community Day Event Planning Form | 300 | 1 | 300 | .066 | 20 |
| Corps Community Day Event Satisfaction Form | 300 | 1 | 300 | .033 | 10 |
| Total | 300 | | 300 | | 30 hours |

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806. Please direct all correspondence to the "attention of the desk officer for HRSA."

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: April 4, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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BILLING CODE 4165-15-P

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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Glucose Regulation.

Date: June 5, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D. G. Patel, PhD., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, patelkg@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: June 13, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Thomas A. Tatham, PhD., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health,

Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, tatham@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 4, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-08285 Filed 4-9-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Closed Meeting

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 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