

[www.cfsan.fda.gov/~comm/expcllst.html](http://www.cfsan.fda.gov/~comm/expcllst.html), which identifies U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what

criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Web site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under the guidance, FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: (1) Name and address of the firm and the manufacturing plant; (2) name, telephone number, and e-mail address

(if available) of the contact person; (3) a list of products presently shipped and expected to be shipped in the next 3 years; (4) identities of agencies that inspect the plant and the date of last inspection; (5) plant number and copy of last inspection notice; and (6) if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

In the **Federal Register** of June 4, 2009 (74 FR 26867), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response, each containing one or more comments. The comments were outside the scope of the comment request in the notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New written requests to be placed on the list	15	1	15	1.5	23
Biannual update	88	1	88	1.0	88
Occasional updates	25	1	25	0.5	13
<b>Total</b>					<b>124</b>

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

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates and occasional updates is based on the FDA's experience maintaining the list over the past 4 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

To date, over 175 producers have sought to be included on the list. FDA estimates that, each year, approximately 15 new firms will apply to be added to the list. We estimate that a firm will require 1.5 hours to read the guidance, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list for a total of 22.5 hours, rounded to 23. Under the guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 88 firms (175 x 0.5 = 87.5, rounded to 88), will resubmit the information to

remain on the list. We estimate that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 88 hours. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 12.5 hours, rounded to 13.

Dated: January 15, 2010.

**David Dorsey**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Advanced Education Nursing Traineeship (AENT) and Nurse Anesthetist Traineeship (NAT) (OMB No. 0915-0305) [Extension]**

The Health Resources and Services Administration (HRSA) provides training grants to educational institutions to increase the number of advanced education nurses through the Advanced Education Nursing Traineeship (AENT) Program and the Nurse Anesthetist Traineeship (NAT) Program.

HRSA developed the AENT and NAT tables for the application guidances and the Nurse Traineeship Database for the two nursing traineeship programs. The AENT and NAT tables are used annually by grant applicants that are applying for AENT and NAT funding. The funds appropriated for the AENT and NAT programs are distributed among eligible institutions based on a formula. Award amounts are based on

enrollment and graduate data reported on the tables and two funding factors (Statutory Funding Preference and Statutory Special Consideration).

The AENT and NAT tables include information on program participants such as the number of enrollees, projected data on enrollees and graduates for the following academic year, number of trainees supported, number of graduates, number of graduates supported and the types of programs they are enrolling into and/or from which they are graduating. AENT and NAT applicants will have a single access point to submit their grant applications including the tables. Applications are submitted in two phases: Grants.gov (Phase 1) and the HRSA Electronic Handbooks (Phase 2). These tables will be available electronically through the HRSA Electronic Handbooks (Phase 2) for applicants to submit their AENT and/or

NAT grant application(s). The tables are also used in the Nurse Traineeship Database which is used by Division of Nursing staff and not the applicants.

Data from the tables will be used in the award determination and validation process. Additionally, the data will be used to ensure programmatic compliance, report to Congress and policymakers on the program accomplishments, and formulate and justify future budgets for these activities submitted to OMB and Congress.

The burden estimate for this project is as follows: AENT increased from 1 hour to 1.5 hours due to the revisions of AENT Tables 1, 2, 3 and 4 to capture comprehensive data to provide for more detailed data analysis of the AENT Program. NAT burden estimate is increased from 1 hour to 1.5 hours in fiscal year 2011 due to the additional data collection.

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
AENT .....	500	1	500	1.5	750
NAT .....	100	1	100	1.5	150
Total .....	600	.....	600	.....	900

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: January 14, 2010.

**Sahira Rafiullah,**

*Deputy Director, Division of Policy Review and Coordination.*

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**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; 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:* National Institute of Mental Health Special Emphasis Panel, Translational Research Center in Behavioral Science.

*Date:* February 19, 2010.

*Time:* 12 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call.)

*Contact Person:* Serena P. Chu, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Rockville, MD 20892-9609. 301-443-0004. [sechu@mail.nih.gov](mailto:sechu@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Identification and Characterization of Sensitive Periods for Neurodevelopment in Studies of Mental Illness. *Date:* February 22-23, 2010. *Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Four Seasons Hotel DTRS Washington, LLC, 2800 Pennsylvania Avenue, NW., Washington, DC 20007.

*Contact Person:* Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609. 301-402-6807. [libbeym@mail.nih.gov](mailto:libbeym@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Eating Disorders.

*Date:* February 23, 2010.

*Time:* 1:30 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call.)

*Contact Person:* Serena P. Chu, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Rockville, MD 20892-9609. 301-443-0004. [sechu@mail.nih.gov](mailto:sechu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)