The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the Agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: November 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–29058 Filed 11–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0002]**

### The Development and Evaluation of Human Cytomegalovirus Vaccines; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration, Center for Biologics Evaluation and Research, the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, and the National Vaccine Program Office are announcing a public workshop entitled ''The Development and Evaluation of Human Cytomegalovirus Vaccines.'' The purpose of the public workshop is to identify and discuss key issues related to the development and evaluation of human cytomegalovirus (HCMV) vaccines. The public workshop will include presentations on HCMV disease and pathogenesis and issues related to vaccine development.

*Date and Time:* The public workshop will be held on January 10 and January 11, 2012, from 8:30 a.m. to 5:30 p.m.

*Location:* The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Pre-registered participants will receive additional information on parking and public transportation with their email registration confirmation.

*Contact Person:* Manen Bishop, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, (301) 827–2000, FAX: (301) 827–3079, email: *CBERTraining@fda.hhs.gov* (Subject line: HCMV Vaccine Workshop).

*Registration:* Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Manen Bishop (see *Contact Person*) or email to *CBERTraining@fda.hhs.gov* (Subject line: HCMV Workshop Registration) by December 12, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Manen Bishop (see *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** HCMV, also known as human herpesvirus 5, infects approximately half of the U.S. population by adulthood. While most infections are without symptoms, the infection is lifelong. However, the disease may become apparent in children who were infected during gestation (congenital HCMV) and in infected individuals with weakened immune systems. Congenital HCMV infection causes mental retardation, learning disabilities, hearing loss, vision loss, and other disabilities. Patients undergoing stem cell or solid-organ transplants are at particularly high risk for severe disease or death from HCMV infection.

An effective vaccine could have a significant impact on rates of congenital anomalies and severe infections caused by HCMV. However, efforts to develop a vaccine against HCMV have not yet been successful.

The public workshop will focus on the status of knowledge about HCMV biology and epidemiology and on vaccine development strategies. Topics for discussion will include: (1) HCMV epidemiology and diagnosis, (2) HCMV immunology and virology, (3) manufacturers' and regulators' perspectives, (4) target populations for a HCMV vaccine, (5) design of clinical trials to study HCMV vaccines in the setting of congenital HCMV and transplants, and (6) next steps toward development of HCMV vaccines.

*Transcripts:* Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: November 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–29006 Filed 11–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request; Application for Collaboration With the NIH Center for Translational Therapeutics (NCTT)

**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 (insert name of NIH Institute or Center), 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.

*Proposed Collection: Title:* Application for collaboration with the NIH Center for Translational Therapeutics (NCTT). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Programs at the NCTT provide opportunities to partner with and gain access to both common and specifically rare and neglected disease through a variety of programs delivering assay development, screening, hit to lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment with the goal of moving promising therapeutics into human clinical trials. NCTT uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. *Frequency of Response:* Four per year. *Affected Public:* Research scientists. *Type of Respondents:* Academic scientists, industry, not-for-profits, government

organizations, patient groups. The annual reporting burden is as follows: *Estimated Number of Respondents:* 170. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* 4. *Estimated Total Annual Burden Hours Requested:* 680.

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| Applicants | 170 | 1 | 4 | 680 |

The annualized cost to respondents is estimated at: $68,000. Capital Costs are $0. Operating Cost is roughly $15,000 for the database to accept and coordinate responses.

*Request For Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. John McKew, Chief, Preclinical Development Branch, NIH Center for Translational Therapeutics, 9800 Medical Center Drive, Building B, Rockville, MD 20850.

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

Dated: November 1, 2011.

**John McKew,**

*Chief, Preclinical Development Branch, NIH Center for Translational Therapeutics, National Human Genome Research Institute, National Institutes of Health.*

[FR Doc. 2011–28965 Filed 11–8–11; 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:* Center for Scientific Review Special Emphasis Panel, Gap Junctions: Program Project Grant Review.

*Date:* December 6–7, 2011.

*Time:* 8 a.m. to 11 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Peter B Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

*Name of Committee:* Biology of Development and Aging Integrated Review Group, International and Cooperative Projects—1 Study Section.

*Date:* December 13, 2011.

*Time:* 12 p.m. to 7 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Grand, 2350 M Street, NW.,Washington, DC 20037.

*Contact Person:* Hilary D Sigmon, Ph.D.,Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594–6377, *sigmonh@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 2, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–28958 Filed 11–8–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; 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 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 Cancer Institute Special Emphasis Panel, Cancer Diagnostic and Therapeutic Agents Enabled by Nanotechnology.

*Date:* November 29, 2011.

*Time:* 8 a.m. to 7 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Savvas C Makrides, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm 8053, Bethesda, MD 20892, (301) 594–1279, *makridessc@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional