

796-0700, e-mail:
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SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow

professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Beth Duvall-Miller (*see DATES and FOR FURTHER INFORMATION CONTACT*).

Dated: February 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-3461 Filed 2-15-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements (OMB No. 0915-0307)—Extension

Title XXVI, Section 2671 of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program), requires that grantees expend 75 percent of Parts A, B, and C Funds on core medical services, including antiretroviral drugs for individuals with HIV/AIDS, identified and eligible under the legislation. In order for Grantees under Parts A, B, and C to be exempted from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA, as required in the Act.

HRSA utilizes standards for granting waivers of the core medical services requirement for the Ryan White HIV/AIDS Program. These standards meet the intent of the Ryan White HIV/AIDS Program to increase access to core medical services, including antiretroviral drugs for persons with HIV/AIDS, and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS, identified and eligible under Title XXVI of the PHS Act. The core medical services waiver uniform standard and waiver request process will apply to Ryan White HIV/AIDS Program Grant Awards under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services waivers will be effective for a 1-year period that is consistent with the grant award period.

Grantees must submit a waiver request with the annual grant application containing the certifications and documentation which will be utilized by HRSA in making determinations regarding waiver requests. Grantees must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all individuals with HIV/AIDS, identified and eligible under Title XXVI of the PHS Act in the service area within 30 days.

The annual estimate of burden is as follows:

Application	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Waiver Request	10	1	10	6.5	65
Total	10	1	10	6.5	65

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 30 days of this notice.

Dated: February 10, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–3528 Filed 2–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date And Time: March 3, 2011, 9 a.m. to 5 p.m. EDT, March 4, 2011, 9 a.m. to 12 p.m. EDT.

Place: Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, March 3 from 9 a.m. to 5 p.m. (EDT) and on Friday, March 4 from 9 a.m. to 12 p.m. (EDT). The public can join the meeting via audio conference call by dialing 1–800–369–3104 on March 3 and March 4 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.
Password: ACCV.

Agenda: The agenda items for the March meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice (DOJ), National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), Center for Biologics, Evaluation and Research (Food and Drug Administration), a discussion on the VICP outreach efforts, and a review of

Vaccine Information Statements (VISs). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, e-mail address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by e-mail, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593 or e-mail: aherzog@hrsa.gov.

Dated: February 10, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–3527 Filed 2–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 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 Allergy and Infectious Diseases Special Emphasis Panel; Ancillary Studies in Immunomodulation Clinical Trials (R01).

Date: March 10, 2011.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: James T. Snyder, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/NIAID, National Institutes of Health, 6700B Rockledge Drive, MSC 7616, Room #3257, Bethesda, MD 20892–7616, 301–435–1614, james.snyder@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Genetics of Lupus.

Date: March 11, 2011.

Time: 11:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, 3136, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Wendy F. Davidson, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–402–8399, davidsonw@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,