

Dated: December 17, 2008.

David A. Drabkin,

Deputy Chief Acquisition Officer, Office of the Chief Acquisition Officer, General Services Administration.

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GENERAL SERVICES ADMINISTRATION

Office of Small Business Utilization; Small Business Advisory Committee; Notification of a Public Meeting of the Small Business Advisory Committee, Subcommittee on Service-Disabled Veteran-Owned Small Businesses

AGENCY: Office of Small Business Utilization, GSA.

ACTION: Notice.

SUMMARY: The General Services Administration (GSA) is announcing a public meeting of the GSA Small Business Advisory Committee, Subcommittee on Service-Disabled Veteran-Owned Small Businesses (the Subcommittee).

DATES: The meeting will take place January 13, 2009. The meeting will begin at 1 p.m. and conclude no later than 4 p.m. that day. The Subcommittee will accept oral public comments at this meeting and has reserved a total of thirty minutes for this purpose. Members of the public wishing to reserve speaking time must contact the DFO in writing at: sbac@gsa.gov or by fax at (202) 501-2590, no later than one week prior to the meeting. Individuals interested in attending the meeting should contact the DFO prior to the meeting date to expedite security procedures for building admittance.

ADDRESSES: GSA Building, 1800 F Street, NW., Washington, DC 20405

FOR FURTHER INFORMATION CONTACT: Lucy Jenkins or Aaron Collmann, Room 6029, GSA Building, 1800 F Street, NW., Washington, DC 20405 (202) 501-1021 or e-mail at sbac@gsa.gov.

SUPPLEMENTARY INFORMATION: This notice is published in accordance with the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463). The purpose of this meeting is to generate topics for future discussion and to hear from interested members of the public on proposals to improve GSA's SDVOB contracting performance.

Topics for this meeting will include but are not limited to welcoming the members to the subcommittee, the members annual ethics briefing and discussion of GSA's Veteran Outreach Program (21 Gun Salute) and

improvements to the program. Information on the full Small Business Advisory Committee can be found online at <http://www.gsa.gov/sbac>.

Dated: December 18, 2008.

Michael J. Rigas,

Associate Administrator, Office of Small Business Utilization, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

AUTHORITY: 42 U.S.C. 300aa-5, Section 2105 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The National Vaccine Program Office (NVPO), a program office within the Office of Public Health and Science, Department of Health and Human Services (HHS), is soliciting nominations of qualified candidates to be considered for appointment as members to the National Vaccine Advisory Committee (NVAC). The activities of this Committee are governed by the Federal Advisory Committee Act (FACA). Management support for the activities of this Committee is the responsibility of the NVPO.

Consistent with the National Vaccine Plan, the Committee advises and makes recommendations to the Assistant Secretary for Health in his capacity as the Director of the National Vaccine Program, on matters related to the Program's responsibilities. Specifically, the Committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; recommends research priorities and other measures to enhance the safety and efficacy of vaccines. The Committee also advises the Assistant Secretary for Health in the implementation of Sections 2102 and 2103 of the PHS Act; and identifies annually the most important areas of government and non-government cooperation that should be considered

in implementing Sections 2102 and 2103 of the PHS Act.

DATES: All nominations for membership on the Committee must be received no later than 5 p.m. EDT on February 2, 2009, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to: Bruce Gellin, M.D., M.P.H., Executive Secretary, NVAC, Office of Public Health and Science, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Hubert H. Humphrey Building; Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, Public Health Advisor, National Vaccine Program Office, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 690-5566; nvpo@hhs.gov.

A copy of the Committee charter which includes the Committee's structure and functions as well as a list of the current membership can be obtained by contacting Ms. Krull or by accessing the NVAC Web site at: <http://www.hhs.gov/nvpo/nvac>.

SUPPLEMENTARY INFORMATION: Committee Function, Qualifications, and Information Required: As part of an ongoing effort to enhance deliberations and discussions with the public on vaccine and immunization policy, nominations are being sought for interested individuals to serve on the Committee. Individuals selected for appointment to the Committee will serve as voting members. The NVAC consists of 17 voting members. The Committee is composed of 15 public members, including the Chair, and two representative members. Public members shall be selected from individuals who are engaged in vaccine research or the manufacture of vaccines, or who are physicians, members of parent organizations concerned with immunizations, representatives of state or local health agencies or public health organizations. Representative members shall be selected from the vaccine manufacturing industry who are engaged in vaccine research or the manufacture of vaccines. Individuals selected for appointment to the Committee can be invited to serve terms of up to four years.

All NVAC members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct authorized Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are

appointed to serve as public members are authorized also to receive honorarium for attending Committee meetings and to carry out other authorized Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive honorarium for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill positions on the NVAC that are scheduled to be vacated in the public member category. The positions are scheduled to be vacated on March 31, 2009.

Nominations

In accordance with the charter, persons nominated for appointment as members of the NVAC should be among authorities knowledgeable in areas related to vaccine safety, vaccine effectiveness, and vaccine supply. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity); (2) a statement from the nominee, bearing an original signature, that, if appointed, he or she is willing to serve as a member of the Committee; (3) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (4) a current copy of the nominee's curriculum vitae.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable. Applications cannot be submitted by facsimile. The names of Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made that a broad representation of geographic areas, gender, ethnic and minority groups, and the disabled are given

consideration for membership on HHS Federal advisory committees. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of NVAC are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: December 8, 2008.

Bruce Gellin,

*Director, National Vaccine Program Office,
Executive Secretary, National Vaccine
Advisory Committee.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0045] (formerly
Docket No. 2004N-0408)

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry,

including its challenges and operations. The purpose of this notice is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit a written or electronic request for participation in this program by January 23, 2009. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, or if your biologics facility responded to a previous RSVP notice announced in the **Federal Register**, you should submit a request to participate in the program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Lonnie Warren Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, email: matt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to improve: (1) Its understanding of current industry practices, and regulatory impacts and needs; and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005, and through these annual notices, is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest, as well as