

efficacy of a tetravalent meningococcal conjugate vaccine, Menactra, manufactured by Aventis Pasteur, Inc. On September 23, 2004, the committee will hear an update on the phase 3 Thai trial of ALVAC vCP 1521 (Aventis Pasteur, Inc.) with AIDSVAX B/E (VaxGen, Inc.) for the prevention of HIV-1 infection.

**Procedure:** On September 22, 2004, from 10 a.m. to 4:30 p.m. and on September 23, 2004, from 9 a.m. to 10:45 a.m. the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 15, 2004. Oral presentations from the public will be scheduled between approximately 2 p.m. and 2:30 p.m. on September 22, 2004, and between approximately 10:15 a.m. and 10:45 a.m. on September 23, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 16, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

**Closed Presentation of Data:** On September 22, 2004, from 8:15 a.m. to 9:45 a.m. and on September 23, 2004, from 11 a.m. to 12:15 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 30, 2004.

**Lester M. Crawford,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 04-20179 Filed 9-2-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Development of Application Guidance for Free Clinics To Sponsor a Volunteer Health Professional for Federal Tort Claims Act (FTCA) Deemed Status and FTCA Coverage for Medical Malpractice Claims

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Solicitation of comments.

**SUMMARY:** In preparation for the development of application guidance for determining the Free Clinics Federal Tort Claims Act (FTCA) Medical Malpractice Program (Program) qualifications, extent of protection, requirements for participation, and application process by which persons can determine if and/or how a volunteer free clinic health professional can be deemed a Public Health Service employee and, therefore, afforded FTCA medical malpractice protections, the Health Resources and Services Administration (HRSA) is offering an opportunity to comment on the draft Program Information Notice (PIN) titled "Federal Tort Claims Act Coverage of Free Clinic Volunteer Health Care Professionals." This Notice is available on HRSA's Bureau of Primary Health Care (BPHC) Web site at <http://www.bphc.hrsa.gov/freeclinicsftca>. This PIN details key definitions, sponsorship requirements, FTCA coverage, and the documentation required for the deeming application.

HRSA believes that consultation with the public is an integral part of the application guidance development effort directed at implementing the Free Clinics FTCA Program.

The opportunity to comment includes (1) Identifying those areas in the guidance that need clarification and/or improvement, and (2) offering suggestions for achieving improvements. This PIN will be effective when issued, and BPHC will use the feedback received under this comment process for future updates to the PIN for the Free Clinics FTCA Program. Comments will be reviewed, analyzed, and summarized for use in implementing the FTCA Free Clinic Volunteer Health Care Professionals deeming process.

**Background:** The purpose of the Program is to provide FTCA medical malpractice protection for eligible volunteer free clinic health professionals. Individuals eligible to

participate in the Program are health care practitioners volunteering at free clinics who meet certain requirements. If the health care practitioner meets the Program requirements, he or she can be "deemed" to be an employee of the Public Health Service and would be protected from non-FTCA medical malpractice lawsuits as a result of the performance of medical, surgical, dental or related functions within the scope of their volunteer work at the free clinic. These related functions may include the conduct in certain clinical studies or investigations.

**Authorizing Legislation:** Section 224 of the Public Health Service Act (42 U.S.C. 233), as amended by Public Law 104-191 (the Health Insurance Portability and Accountability Act of 1996 (HIPAA)). Section 194 of HIPAA amended the Act by adding subsection 224(o), which provides for liability protection for certain free clinic health professionals.

**DATES:** Please send comments no later than October 4, 2004. The comments should be addressed to Sam Shekar, M.D., M.P.H., Associate Administrator for Primary Health Care, Health Resources and Services Administration, 11th Floor, 4350 East West Highway, Bethesda, Maryland 20814.

**FOR FURTHER INFORMATION CONTACT:** Program Director, Federal Tort Claims Act Medical Malpractice Program, Division of Clinical Quality, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, Bethesda, Maryland 20814 (Phone: 301-594-0818 or e-mail: [FreeClinicsFTCA@HRSA.GOV](mailto:FreeClinicsFTCA@HRSA.GOV)).

Dated: August 30, 2004.

**Elizabeth M. Duke,**  
*Administrator.*

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## 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. Appendix 2), 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