Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card (also referred to as a ''laser visa'') issued in accordance with the requirements of regulations prescribed under a specific section of the Immigration and Nationality Act.

Type of Information Collection Request: New collection; *Title of Information Collection:* Federal Funding of Emergency Health Services (Section 1011): Enrollment Application; *Use:* This enrollment application will: identify a provider's potential interest in seeking payment under section 1011, but does not require the hospital to seek that payment; will allow hospitals to make a payment election, as required by section 1011(c)(3)(C); allow CMS to obtain necessary financial information to effectuate payments and issue the appropriate tax information; establish the State of service for each provider; allow CMS to verify that the hospital, physician or provider of ambulance services is currently enrolled as a Medicare provider; require hospitals to notify physicians of its election under (c)(3)(C) of section 1011; require hospitals electing hospital and physician payments to provide reimbursement to physicians in a prompt manner; prohibit hospitals electing to receive both hospital and physician payments from charging an administrative or other fee to physicians for the purpose of transferring reimbursement to physicians (*see* section 1011(c)(3)(D)); establishes the provider's obligation to repay any assessed overpayment within 30 days of notification by CMS; and, informs a provider that applicable Federal laws apply to submission of false claims.

Form Number: CMS–10115 (OMB#: 0938—New); *Frequency:* Other: as needed; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal govt.; *Number of Respondents:* 62,500; *Total Annual Responses:* 62,500; *Total Annual Hours:* 31,250.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Dated: August 31, 2004.

John P. Burke, III,

Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–20242 Filed 9–1–04; 1:58 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Supplemental New Animal Drug Application; Ivermectin and Praziquantel Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Virbac AH, Inc. The supplemental NADA provides for use of an ivermectin and praziquantel oral paste for the treatment and control of various species of internal parasites in mares intended for breeding purposes.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 7613, filed a supplement to approved NADA 141–215 for EQUIMAX (ivermectin 1.87%/praziquantel 14.03%) Paste, used in horses for the treatment and control of various species of internal parasites. The supplemental NADA provides for use of EQUIMAX Paste in mares intended for breeding purposes. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of July 30, 2004. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning July 30, 2004.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 25, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–20178 Filed 9–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 22, 2004, from 8:15 a.m. to 4:30 p.m. and on September 23, 2004, from 9 a.m. to 12:15 p.m.

Location: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 22, 2004, the committee will consider the safety and

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]

BILLING CODE 4160–01–S

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*.)

Dated: August 30, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–20180 Filed 9–2–04; 8:45 am]

BILLING CODE 4165–15–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. 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