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