DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation Medicare Program; Meeting of the Technical Advisory Panel on Medicare Trustee Reports

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Technical Advisory Panel on Medicare Trustee Reports (Panel). Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Panel will discuss the long-term rate of change in health spending and may make recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the long run. The Panel's discussion is expected to be very technical in nature and will focus on the actuarial and economic methods by which Trustees might more accurately measure health spending. Although panelists are not limited in the topics they may discuss, the Panel is not expected to discuss or recommend changes in current or future Medicare provider payment rates or coverage policy.

DATES: September 15, 2004, 8 a.m.–5 p.m., e.s.t.

ADDRESSES: The meeting will be held at HHS headquarters at 200 Independence Ave., SW., 20201, Room 425A.

Comments: The meeting will allocate time on the agenda to hear public comments. In lieu of oral comments, formal written comments may be submitted for the record to Andrew Cosgrove, OASPE, 200 Independence Ave., SW., 20201, Room 443F.8. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Andrew Cosgrove (202) 205–8681, *andrew.cosgrove@hhs.gov*. Note: Although the meeting is open to the public, procedures governing security procedures and the entrance to Federal buildings may change without notice. Those wishing to attend the meeting should call or e-mail Mr. Cosgrove by September 8, 2004, so that their name may be put on a list of expected attendees and forwarded to the security officers at HHS Headquarters.

SUPPLEMENTARY INFORMATION: On April 22, 2004, we published a notice announcing the establishment and requesting nominations for individuals to serve on the Panel. The panel members are: Mark Pauly, Edwin Hustead, Alice Rosenblatt, Michael Chernew, David Meltzer, John Bertko, and William Scanlon.

Topics of the Meeting: The Panel is specifically charged with discussing and possibly making recommendations to the Medicare Trustees on how the Trustees might more accurately estimate the long-term rate of health spending in the United States. The discussion is expected to focus on highly technical aspects of estimation involving economics and actuarial science. Panelists are not restricted, however, in the topics that they choose to discuss.

Procedure and Agenda: This meeting is open to the public. Interested persons may observe the deliberations and discussions, but the Panel will not hear public comments during this time. The Commission will also allow an open public session for any attendee to address issues specific to the topic.

Authority: 42 U.S.C. 217a; Section 222 of the Public Health Services Act, as amended. The panel is governed by 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.

Dated: August 26, 2004.

Michael J. O'Grady,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 04–20161 Filed 9–2–04; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10115]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, submitted the following collection for emergency review and approval.

We requested an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with provisions of section 1011 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We cannot reasonably comply with the normal clearance procedures because of the statutory implementation date of September 1, 2004.

OMB evaluated the collection for necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

OMB approved the collection emergency review of the information collection referenced below on August 31, 2004. OMB approved CMS's request of this collection for a 180-day approval period.

Note: CMS will issue its payment methodology shortly.

Background

Section 1011 provides $250 million per year for fiscal years (FY) 2005–2008 for payments to eligible providers for emergency health services provided to undocumented aliens and other specified aliens. Two-thirds of the funds will be divided among all 50 States and the District of Columbia based on their relative percentages of undocumented aliens. One-third will be divided among the six States with the largest number of undocumented alien apprehensions.

From the respective State allotments, payments will be made directly to hospitals, certain physicians, and ambulance providers for some or all of the costs of providing emergency health care required under section 1867 and related hospital inpatient, outpatient and ambulance services to eligible individuals. Eligible providers may include an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization. A Medicare critical access hospital (CAH) is also a hospital under the statutory definition. Payments under section 1011 may only be made to the extent that care was not otherwise reimbursed (through insurance or otherwise) for such services during that fiscal year.

Payments may be made for services furnished to certain individuals described in the statute as: (1) Undocumented aliens; (2) aliens who have been paroled into the United States at a port of entry for the purpose of receiving eligible services; and (3)

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