clinical endpoints for trials in heavily pretreated patients.

5. Comments on any additional considerations for clinical trials in treatment experienced pediatric patients.

These submissions should contain docket number 00N–1585, and they should be made to the Dockets Management Branch address provided previously in this document.

Procedure: 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 January 4, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 4, 2001, 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.

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

Dated: December 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–32889 Filed 12–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs 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). The meeting will be open to the public.

Name of Committee: Antiviral Drugs 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 January 10, 2001, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–227, Cancidas™ (caspofungin) Injection, Merck Research Laboratories, indicated for treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies.

Procedure: 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 January 4, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 4, 2001, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the January 10, 2001, meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Antiviral Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: December 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–32890 Filed 12–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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). The meeting will be open to the public.

Name of Committee: Arthritis 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 February 7, 8, and 9, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, or e-mail reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 7, 2001, the committee will discuss new drug application (NDA) 20–998/S009, Celebrex® (celecoxib, G. D. Searle & Co.) approved for the treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. The discussion is for modification of the label based on the results of the CLASS Trial, a study of the incidence of significant upper gastrointestinal effects. On February 8, 2001, the committee will discuss NDA 21–042/S007, Vioxx™ (rofecoxib, Merck Research Laboratories) approved for the treatment of signs and symptoms of osteoarthritis and the management of acute pain. The discussion is for changes in the product label related to results of the VIGOR Trial concerning clinical gastrointestinal events. On February 9, 2001, the committee will discuss NDA 20–905/S006, Arava™ (leflunomide, Aventis) approved for the treatment of active rheumatoid arthritis. The discussion is for an indication to prevent disability as evidenced by improved physical function.

Procedure: 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 January 30, 2001. Oral presentations from the public will be scheduled between approximately 11 and 11:30 a. m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 30, 2001, 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.

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

Dated: December 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–32891 Filed 12–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand 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). The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on January 22, 2001, 1 p.m. to 4:30 p.m., January 23, 2001, 8:30 a.m. to 4:30 p.m., and January 24, 2001, 8:30 to 12 noon.

Location: Parklawn Bldg., 5600 Fishers Lane, conference room K, Rockville, MD.

Contact Person: Barbara J. Jewell, Food and Drug Administration, 5600 Fishers Lane, rm. 16–53, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide final comments and recommendations on the scope of work for the physical examinations and final report preparation for the sixth and final round of the Air Force Health Study.

Procedure: 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 January 10, 2001. Oral presentations from the public will be scheduled on January 22, 2001, between approximately 3 p.m. to 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 10, 2001, 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.

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

Dated: December 15, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–33022 Filed 12–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies (TSE) 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: Transmissible Spongiform Encephalopathies (TSE) 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 January 18, 2001, 8:30 a.m. to 5:30 p.m. and January 19, 2001, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Sheila D. Langford, 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 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 18, 2001, the committee will discuss whether recent information about new variant Creutzfeldt-Jakob disease (nvCJD) in France and bovine spongiform encephalopathy in France and other European countries suggests a need to reconsider FDA policies on suitability of blood donors who lived or traveled in those countries. In the afternoon, the committee will discuss the risks of Creutzfeldt-Jakob disease (CJD) and vCJD transmission by human cells, tissues and cellular and tissue-based products intended for implantation, transplantation, infusion, or transfer that are currently or proposed to be regulated by FDA, and the possible deferral of donors who have resided in the United Kingdom. On January 19, 2001, the committee will discuss issues related to deer and elk infected with or exposed to chronic wasting disease in the United States and potential for human exposure. In the afternoon, the committee will discuss whether a history of possible exposure to various animal transmissible spongiform encephalopathy agents should be considered by FDA in determining suitability of blood donors.

Procedure: On January 18, 2001, from 8:30 a.m. to 5 p.m. and January 19, 2001, from 8:30 a.m. to 5:30 p.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 January 12, 2001. Oral presentations from the public will be scheduled between approximately 10:30