may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 18, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–16850 Filed 6–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective 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: Anti-Infective 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 July 29, 30, and 31, 1998, 8 a.m. to 5 p.m.

Location: Gaithersburg Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Ermona B. McGoodwin, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss documents on ''Guidance to Industry'' being developed by the Office of Drug Evaluation IV's Division of Anti-Infective Drug Products and the Division of Special Pathogens and Immunologic Drug Products. Copies of these draft guidance documents can be obtained from the Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573, or requested by FAX at 301–827–4577. Electronic versions of these guidance documents will be available via Internet using the World Wide Web (www). To access the documents on the www, connect to CDER Home Page at http://www.fda.gov/cder/guidance.htm.

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 July 22, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 29, 30, and 31, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 22, 1998, 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: June 18, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–16934 Filed 6–24–98; 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 regulatory issues.

Date and Time: The meeting will be held on August 7, 1998, 8 a.m. to 5 p.m.

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

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, 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: The committee will discuss the safety and efficacy of new drug application 20–905 Arava (leflunomide, Hoechst Marion Roussel, Inc., Germany) for the treatment of rheumatoid arthritis.

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 July 30, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 30, 1998, 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: June 15, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–16837 Filed 6–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic 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: Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic 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 July 22, 1998, 8 a.m. to 5 p.m.

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

Contact Person: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 20–961, Vitravene® (fomivirsen sodium intravitreal injection, ISIS Pharmaceuticals), for treatment of cytomegalovirus (CMV) retinitis in patients with acquired immune deficiency syndrome (AIDS).

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 July 17, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 1998, 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: June 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–16851 Filed 6–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; Altered System of Records

AGENCY: National Institutes of Health, HHS.

ACTION: Notification of an altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of proposal to alter an existing system of records 09–25–0036, ''Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/OER and HHS/NIH/CMO.'' The system is altered by including contractor past performance information as a new category of records; adding consultants and contractors as individuals covered by the system; and including a new routine use which allows NIH to share information it collects on contractor past performance information with other Federal agencies.

DATES: The NIH invites interested parties to submit comments on the proposed internal and routine uses on or before July 27, 1998. The NIH sent a Report of the Altered System to the Congress and to the Office of Management and Budget (OMB) on June 19, 1998. The alteration of this system of records will be effective 40 days from the date submitted to the OMB, unless NIH receives comments which would result in a contrary determination.

ADDRESSES: Please submit comments to: NIH Privacy Act Officer, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, 301–496–2832. (This is not a toll free number.)

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: NIH Privacy Act Officer, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, 301–496–2832. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) proposes to alter an existing system of records 09–25–0036, ''Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO.'' The system is altered by including contractor past performance information as a new category of records; adding consultants and contractors as individuals covered by the system; including a new routine use which allows NIH to share information it collects on contractor past performance information with other Federal agencies; and editorial changes to accommodate normal updating changes.

The purposes of this system of records are to (1) support centralized grant programs of the Public Health Service by providing services in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting; maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program; maintain current and historical information pertaining to the establishment of chartered advisory committees of the National Institutes of Health and the appointment or designation of their members; and maintain current and historical information pertaining to contracts awarded by the National Institutes of Health, and performance evaluations on NIH contracts and contracts awarded by other Federal agencies that participate in the NIH Contractor Performance System.

This system will comprise records that contain names, applications, grant or contract ID number, contractor tax ID number, awards, trainee appointments, current and historical information pertaining to chartered advisory committees, and past performance information pertaining to contractors.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act regulations. The System Managers will control access to the data. Authorized users will be granted access only to those records within their specific area of responsibility. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are NIH extramural and committee management staff, NIH contract management staff, and Federal acquisition personnel. One-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System Manager. Records may be stored on hard copy, discs and magnetic tapes, and in other machine-readable format, regardless of physical form or characteristics. Manual and computerized records will be maintained in accordance with the standards of Chapter 45–13 of the HHS General Administration Manual, ''Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf:45–13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System Manager or other