Diagnostic Systems chemistry systems (i.e., COBAS MIRA® , COBAS MIRA S®, and COBAS MIRA® Plus) for the quantitative analysis of cyclosporine (CsA) in human whole blood as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplant patients.

On November 16, 1992, the Clinical Chemistry and Toxicology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On October 2, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 21, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 20, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–7134 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 7, 1997, 8:30 a.m., Corporate Bldg., conference rm. 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 1–800–228–9290 or 301–590–0044 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Christie Wyatt, KRA Corp., 301–495–1591, ext. 267.

Type of meeting and contact person. Closed committee deliberations, 8:30 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 1:30 p.m.; closed presentation of data, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 3:30 p.m.; John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory System Devices Panel, code 12625. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 1, 1997, 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 required to make their comments.

Open committee discussion. The committee will discuss a new premarket notification (510(k)) for a transtelephonic cardiac event monitor for over-the-counter use (nonprescription). This device has previously been cleared by the agency for prescription use.

Closed presentation of data. The sponsor may present trade secret and/or confidential commercial information regarding the cardiac monitor. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information relevant to cardiovascular system devices that are currently being evaluated by FDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Antiviral Drugs Advisory Committee

Date, time, and place. April 14, 1997, 8:30 a.m.; Armory Place, 925 Wayne Ave., rm. 204, Silver Spring, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5:30 p.m.; Rhonda W. Stover, 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 Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 7, 1997, 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 required to make their comments.

Open committee discussion. The committee will discuss data relevant to a supplemental new drug application for the approved drug, Amphotec™, (amphotericin B cholesteryl sulfate complex, Sequus Pharmaceuticals, Inc.), for use in the empiric therapy of febrile neutropenic patients.

Closed committee deliberations. The committee will review trade secret and/or confidential information relevant to pending investigational new drugs and drug development plans. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Joint Meeting of the Vaccines and Related Biological Products Advisory Committee and the Antiviral Drugs Advisory Committee

Date, time, and place. April 15, 1997, 7:45 a.m., Armory Place, 925 Wayne Ave., rm. 103, Silver Spring, MD. The meeting will move to rm. 204 (same location) at 1 p.m.

Type of meeting and contact person. Open public hearing, 7:45 a.m. to 8:15 a.m. for the Vaccines and Related Biological Products Advisory Committee in room 103, unless public participation does not last that long; closed committee deliberations, 8:15 a.m. to 1 p.m.; closed joint committee deliberations in room 204, 1 p.m. to 5:30 p.m.; open public hearing, 5:30 p.m. to 6 p.m., unless public participation does not last that long; Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington DC area), Vaccines and Related Biological Products Advisory Committee, code 12388; Antiviral Drugs Advisory Committee, code 12531. Please call the hotline for information concerning any possible changes.

General function of the committees. The Vaccines and Related Biological Products Advisory Committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases. The Antiviral Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by April 8, 1997, 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 required to make their comments.

Closed committee deliberations. The committees will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications or product licensing applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will

be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–7188 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Technical Electronic Product Radiation Safety Standards Committee

Date, time, and place. April 8 and 9, 1997, 8:30 a.m., Corporate Bldg., conference rm. 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 800–228–9290 or 301–590–0044 and reference the FDA Advisory Committee meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Christie Wyatt, KRA Corp., 301–495–1591, ext. 267.

Type of meeting and contact person. Open committee discussion, April 8, 1997, 8:30 a.m. to 10:15 a.m.; open public hearing, 10:15 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 3 p.m.; open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 5 p.m.; open committee discussion, April 9, 1997, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 2:15 p.m.; Orhan H. Suleiman, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Technical Electronic Product Radiation Safety Standards Committee, code 12399. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the