FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DAUNOXOME® (daunorubicin citrate). DAUNOXOME® is indicated as a first line cytotoxic therapy for advanced human immunodeficiency virus (HIV)-associated Kaposi's sarcoma. DAUNOXOME® is not recommended in patients with less than advanced HIV-related Kaposi's sarcoma. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for DAUNOXOME® (U.S. Patent Nos. 5,435,989; 5,441,745; and 5,019,369) from NeXstar Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patent's eligibilities for patent term restoration. In letters dated December 2, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DAUNOXOME® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DAUNOXOME® is 2,771 days. Of this time, 1,629 days occurred during the testing phase of the regulatory review period, while 1,142 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 8, 1988. The applicant claims September 29, 1988, as the date the investigational new drug application (IND) for DAUNOXOME® (IND 31,927) became effective. However, FDA records indicate that the effective date for IND 31,927 was September 8, 1988, which was 30 days after FDA received the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: February 22, 1993. The applicant claims February 18, 1993, as the date the new drug application (NDA) for DAUNOXOME® (NDA 50–704) was initially submitted. However, FDA records indicate that NDA 50–704 was submitted on February 22, 1993.

3. *The date the application was approved*: April 8, 1996. FDA has verified the applicant's claim that NDA 50–704 was approved on April 8, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 258 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 20, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 17, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–7135 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0082]

Behring Diagnostics, Inc.; Premarket Approval of EMIT® 2000 Cyclosporine Specific Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Behring Diagnostics, Inc., San Jose, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the EMIT® 2000 Cyclosporine Specific Assay. After reviewing the recommendation of the Clinical Chemistry and Toxicology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 2, 1996, of the approval of the application.

DATES: Petitions for administrative review by April 21, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Cornelia B. Rooks, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2436.

SUPPLEMENTARY INFORMATION: On June 29, 1992, Syva Co., San Jose, CA 95161–9013, submitted to CDRH an application for premarket approval of the EMIT® 2000 Cyclosporine Specific Assay. The device is a homogeneous enzyme immunoassay and is indicated for in vitro diagnostic use on the Roche

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)).