C. Due Dates

Members selected for review must submit completed Community Support Statements to their FHLBanks no later than August 30, 1996.

In completing the Statement, the FHLBank will provide the member with a Community Support Statement form and written instructions. At that time, the FHLBank will also notify the member with a Community Support Statement form and written instructions and will offer assistance to the member in completing the Statement. The FHLBank will only review Statements for completeness, as the Housing Finance Board will conduct the actual review.

D. Notice to Members Selected

Within 15 days of this Notice's publication in the Federal Register, the individual FHLBanks will notify each member selected to be reviewed that the member has been selected and when the member must return the completed Community Support Statement. At that time, the FHLBank will provide the member with a Community Support Statement form and written instructions and will offer assistance to the member in completing the Statement. The FHLBank will only review Statements for completeness, as the Housing Finance Board will conduct the actual review.

E. Notice to Public

At the same time that the FHLBank members selected for review are notified of their selection, each FHLBank will also notify community groups and other interested members of the public. The purpose of this notification will be to solicit public comment on the Community Support records of the FHLBank member pending review.

Any person wishing to submit written comments on the Community Support performance of a FHLBank member under review in this quarter should send those comments to the member's FHLBank by the due date indicated in order to be considered in the review process.

By the Federal Housing Finance Board.
Dated: July 9, 1996.

Rita I. Fair,
Managing Director.

BILLING CODE 6725-01-P

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to

contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.


S.A.C. International Forwarding, Inc., 8442 NW 70th Street, Miami, FL 33166, Officer: Marianela Villar Izquierdo, President.

Dated: July 11, 1996.

Joseph C. Polking,
Secretary.

BILLING CODE 6730-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 96M-0237]

Behring Diagnostics, Inc.; Premarket Approval of MicroTrak II IgM Anti-HAV EIA

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 MicroTrak II IgM Anti-HAV EIA. FDA’s Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 13, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 16, 1996.

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: Sharon L. Hansen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION: On April 9, 1992, Behring Diagnostics, Inc., San Jose, CA 95161–9013, submitted to CDRH an application for premarket approval of MicroTrak II IgM Anti-HAV EIA. The MicroTrak II IgM Anti-HAV EIA is an enzyme immunoassay (EIA) intended for in vitro diagnostic use in the qualitative detection of immunoglobulin M (IgM) antibodies to hepatitis A virus (IgM anti-HAV) in human serum or plasma. This device is for use as an aid in the diagnosis of acute or recent hepatitis A infection (usually 6 months or less).

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Microbiology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On May 13, 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 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 part 12 (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 § 10.33(b) (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 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 August 16, 1996, 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), 360(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: June 5, 1996.

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

FOR FURTHER INFORMATION CONTACT: Dorothy B. Abel, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262.

SUPPLEMENTARY INFORMATION: On October 4, 1994, Schneider (USA) Inc., Plymouth, MN 55442, submitted to CDRH an application for premarket approval of the WALLSTENT® TIPS Endoprosthetics. The device is an endovascular stent and is indicated for creation of an endoprosthetic anastomosis between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques.

In accordance with the provisions of section 515(c)(2)(A) of the act (21 U.S.C. 360e(c)(2)(A)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee. FDA concluded that the review by two outside review bodies was sufficient to identify the issues associated with the device and that sufficient guidance in the