

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), 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: June 5, 1996.

Joseph A. Levitt,

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

[FR Doc. 96-18068 Filed 7-16-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96M-0238]

Schneider (USA) Inc.; Premarket Approval of WALLSTENT® Transjugular Intrahepatic Portosystemic Shunt (TIPS) Endoprosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Schneider (USA) Inc., Plymouth, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the WALLSTENT® TIPS Endoprosthesis. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 29, 1995, 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: 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 Endoprosthesis. The device is an endovascular stent and is indicated for creation of intrahepatic shunt connections 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

evaluation of the safety and effectiveness had been provided by these review bodies. In addition, the safety and effectiveness of stents used for other indications has been the subject of four FDA advisory committee meetings.

On September 29, 1995, 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), 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: June 21, 1996.

Joseph A. Levitt,

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

[FR Doc. 96-18071 Filed 7-16-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Provider/Supplier Enrollment Application; *Form No.:* HCFA-855; *Use:* This information is needed to enroll providers/suppliers by identifying them, verifying their qualifications and eligibility to participate in Medicare, and to price and pay their claims; *Frequency:* Other (Initial Application/recertification); *Affected Public:* Business or other for profit, not for profit institutions, and federal government; *Number of Respondents:* 165,000; *Total Annual Responses:* 165,000; *Total Annual Hours:* 370,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov>, or to obtain the supporting statement and any related forms, E-mail your request, including

your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 9, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96-18094 Filed 7-16-96; 8:45 am]

BILLING CODE 4120-03-P

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA-2082; *Use:* The data reported in the HCFA-2082 are the basis of actuarial forecasts for Medicaid service utilization and costs; of analyses and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from HCFA components, the Department, Congress and other customers; *Frequency:* Annually; *Affected Public:* State, local,