SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' This guidance is intended to provide direction to manufacturers of devices who intend to modify their devices and are in the process of deciding whether the modification requires a new premarket notification submission (510(k)).

DATES: Written comments on this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Copies of a facsimile of the guidance, are available from the Division of Small Manufacturers Assistance (DSMA) Facts on Demand, Center for Devices and Radiological Health (CDRH), 1–800–899–0381. Copies of the guidance may also be obtained from the World Wide Web at http://www.fda.gov/cdrh administered by DSMA and are available to anyone with a video terminal or personal computer (1–800–252–1366). Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION: On April 8, 1994, FDA circulated for comment the first draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The draft guidance was intended to provide direction to manufacturers on deciding when to submit a new 510(k) for changes to an existing device. The April 8, 1994, draft guidance was the subject of a May 12, 1994, FDA teleconference and the subject of discussion at several trade and industry association meetings.

FDA received over 60 comments regarding the April 8, 1994, draft guidance. Based on the comments received, FDA developed an August 1, 1995, second draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' FDA received 11 comments regarding the October 16, 1996, draft guidance. The comments supported the October 16, 1996, draft guidance and suggested that FDA make the following changes: (1) Include the recent publication of the Quality Systems Regulation; (2) add more references for definition and as a referral to other guidance documents; (3) give more examples and explanation of materials, particularly with labeling changes and changes in material for in vitro devices; (4) update Appendix A on suggested material terminology to reflect latest industry comment on the biomaterials compendium; and (5) correct the logic flow in the materials change chart.

Guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the guidance is not being issued under the authority of current § 10.90(b), and it does not create or confer any rights, privileges, or benefits for or on any person, nor does it operate to bind FDA or device manufacturers in any way.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered to determine if further revision of the guidance is warranted.

Dated: February 4, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–4303 Filed 2–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0054]

Schneider (USA), Inc.; Premarket Approval of WALLSTENT® Iliac 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., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the WALLSTENT® Iliac Endoprosthesis. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 28, 1996, of the approval of the application. In addition, the WALLSTENT® Iliac Endoprosthesis requires tracking under the act as amended by the Safe Medical Devices Act of 1990.

DATES: Petitions for administrative review by March 24, 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: Judy J. Danielson, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On June 9, 1994, Schneider (USA), Inc., Minneapolis, MN 55432, submitted to CDRH an application for premarket approval of the WALLSTENT® Iliac Endoprosthesis. The device is a peripheral stent and is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are less than or equal to 10 centimeters in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as: An inadequate angiographic and/or hemodynamic result as defined by a 30 percent or greater residual stenosis after PTA, lesion recoil, or intimal flaps; flow limiting dissections post PTA longer than the initial lesion length; or a 5 mmHg or greater mean transtenotic pressure gradient post PTA.

On March 4, 1996, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On May 28, 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.

Under section 519(e) of the act (21 U.S.C. 360i(e)) as amended by the Safe Medical Devices Act of 1990, manufacturers of certain types of devices are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. FDA has identified the above device as a new generic type of device requiring tracking. FDA is providing a 30-day period for interested persons to submit to the Dockets Management Branch (address above) written comments regarding the agency's position that this new generic type of device requires tracking.

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 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 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 March 24, 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: January 16, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–4228 Filed 2–20–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–462 A/B]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 summary of proposed collections for public comment. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Adverse Action Extract; *Form No.:* HCFA–462A/B; *Use:* This form is used by HCFA surveyors (State Health Department surveyors and other HCFA agents) to record which types of adverse actions are imposed against laboratories. The form will also serve to track dates of the impostion of adverse actions, dates on which a laboratory corrects deficiences, and all appeals activity. *Frequency:* Biennially; *Affected Public:* Not-for-profit institutions, Federal Government, State, Local or Tribal Govt; *Number of Respondents:* 2,500; *Total Annual Responses:* 2,500; Total Annual Hours: 5,625

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/regs/prdact95.htm, 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 Analysis and Planning Staff, Attention: John Rudolph, Room C2–25–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 13, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–4338 Filed 2–20–97; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–841–853]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), 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 the 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