document should be sent by mail or facsimile to: Nancy Tips, NCEH/CDC, Mailstop F42, 4770 Buford Highway, N.E., Atlanta, GA, 30341–3724, facsimile (770) 488–7335.

SUPPLEMENTARY INFORMATION: Childhood lead poisoning is a major preventable environmental health problem in the United States. Since 1975, when CDC issued its first comprehensive guidelines for preventing lead poisoning in children, ''Increased Lead Absorption and Lead Poisoning in Young Children,'' CDC has worked with public health agencies, child health-care providers, and various concerned groups to prevent lead poisoning in young children. Other editions of the guidelines have been published in 1975, 1978, 1985, and 1991. Each revision has incorporated new scientific and practical information on how best to reduce the adverse effects of lead on the health of young children. This draft guidance is narrower in scope than the 1991 edition of ''Preventing Lead Poisoning in Young Children.'' It does not modify CDC's position on adverse health effects caused by lead. Instead, it makes recommendations to improve the use of screening to prevent lead poisoning among young children. These recommendations are needed because data indicate that many children, especially those living in older housing, continue to be heavily exposed to lead, whereas the average exposure of children in the United States has substantially declined. To address this situation, the recommendations in this guidance are intended to increase the screening and follow-up care of children who most need these services and to ensure that prevention approaches are appropriate to local conditions. The audience for this guidance includes State and local public health officials, who will make screening recommendations for their jurisdictions, and pediatricians and other child health-care providers, public health agencies, and health care organizations, including managed care organizations.

Dated: February 14, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–4281 Filed 2–20–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 97N–0025]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by March 24, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Medical Devices Standards Activities Report (OMB Control Number 0910–0219—Extension)

FDA is collecting information necessary to update a comprehensive listing of current national and international standards activities in the field of medical devices. The collection of this information is authorized by section 514(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(4)(B)), which requires FDA to consult with other nationally or internationally recognized standard-setting entities, including other Federal agencies concerned with standard-setting, in carrying out its responsibility to establish special controls for medical devices. This report is used by approximately 39 standards-developing organizations to coordinate their standards activities. This coordination prevents duplication of effort and insures efficient and expeditious management of standards development. Over 700 copies of this report are used by government, hospitals, libraries, industry, private citizens, and State and local government agencies, including FDA, to keep abreast of standards development activities and current technology concerning the safety of medical devices. Without the report, there would be duplication of standards efforts by voluntary standards organizations because there is no other publication that can be easily referenced to ascertain if a certain medical device standard is being or has been developed.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
39	0.5	19.5	3	58.5

There are no capital costs or operating and maintenance costs associated with this collection of information.

This collection occurs biennially and is voluntary. There are 39 national and international organizations with one report each reporting period.

Dated: February 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4227 Filed 2–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0283]

Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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.