Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On December 7, 1990, Johnson and Johnson Interventional Systems, Co., Warren, NJ 07059, submitted to CDRH an application for premarket approval of PALMAZ-SCHATZ™ Balloon-Expandable Stent. The PALMAZ-SCHATZ™ Balloon-Expandable Stent is indicated for use in a group of selected patients eligible for balloon angioplasty (see Individualization of Treatment, which is available for examination at the Dockets Management Branch (address above)) with symptomatic ischemic heart disease due to discrete (length less than 15 millimeter (mm)), *de novo* native coronary artery lesions with a reference vessel diameter in the range of 3 to 4 mm. In this patient population, stenting the coronary artery produces a larger luminal diameter, maintains arterial patency, and reduces the incidence of restenosis at 6 months as compared with balloon angioplasty. The stent, however, represents a permanent implant into the coronary artery. One year and longer followup is not well characterized.

On May 3, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On August 2, 1994, 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 Federal Food, Drug, and Cosmetic Act (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 August 11, 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: May 29, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–17975 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NLM Online Application Packet

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NLM Online Application Packet. *Type of Information Collection Request:* Extension of OMB No. 0925–0223. Expires 08/31/97. *Need and Use of Information Collection:* The NLM uses the information provided by individuals and institutions for MEDLARS online system user code assignments and invoices for system use. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; businesses or other for profit; State or local governments; Federal agencies; Non-profit institutions; Small businesses or organizations. *Type of Respondents:* Organizations, Health Care Providers, Students. The annual reporting burden is as follows: *Estimated Number of Respondents annually:* 1,800. *Estimated Number of Responses per Respondent:* 1: *Average Burden Hours Per Response:* 0.0833 hours; and *Estimated Total Annual Burden Hours Requested:* 149.94. *The annualized cost to respondents is estimated at:* $1,499. There are no capital costs to report. There are no operating or maintenance costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION:

To request additional information on the proposed collection of information or to obtain a copy of the data collection instrument, contact Carolyn Tilley, Head, Medlars Management Section, BSD, LO, NLM, NIH, Building 38A, Room 4N–04, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number (301) 402–1076. You may also e-mail your request to: carolyn__tilley@ccmail.nlm.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 1, 1997.

Donald C. Poppke,

Executive Officer, NLM.

[FR Doc. 97–18007 Filed 7–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Drug Accountability Record

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* Drug Accountability Record (Form NIH 2564) and Transfer Investigation Drug Record (NIH form 2564–1). *Type of Information Collection Request:* Extension, with no Changes OMB No. 0925–0240, Expiration Date 10/31/97. *Need and Use of Information Collection:* Food and Drug Administration (FDA) regulations require investigators to establish a record of the receipt, use and disposition of all investigational agents. The National Cancer Institute, NCI, as a sponsor of investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The Transfer Investigational Drug Form (NIH 2564–1) permits intra-institutional transfer of drugs to other approved investigators for other approved protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator once every three years. All comparisons are done with the intention of ensuring protocol, patient and drug compliance for patient safety and protections. *Frequency of Response:* Daily. *Affected Public:* state or local governments, businesses or other for-profit, Federal agencies or employees, non-profit institutions, and small business or organizations. *Type of Respondents:* Investigators, pharmacist, nurses, pharmacy technicians, data manager. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows:

Federal Burden: 1700 audits are conducted of clinical research sites, a minimum of three Drug Accountability Forms are reviewed at each audit. Each form requires ½ hour to review.

Number of Respondents: 1700.

Number of responses per Respondent: 3.

Average Burden per Response: 0.5 hours.

Annual Burden Hours: 18,250 hours.

Clinical Trial Site Burden: The annualized respondents' burden for record keeping is estimated to require 3,650 hours for drug accountability and 120 hours for drug transfer. The reporting burden is the average time (4 minutes or 0.1 hours) required to complete the transfer investigation drug form multiplied by the number of forms completed annually. The record keeping burden represents an average time required for multiple entries (4 minutes or 0.1 hour per entry) on the drug accountability form, the average number of forms maintained by each record keeper and the number of record keepers. These estimates are based on the 36,500 items shipped by the PMB and the 1,200 items transfer approvals in calendar year 1996.

Drug Transfer Forms

Number of Respondents: 1200.

Number of response per Respondent: 1.

Average Burden per Response: 0.1.

Annual Burden Hours: 120 hours.

Drug Accountability Forms

Number of Record Keepers: 4560.

Number of responses per Respondent: 8.

Average Burden per Response: 0.1.

Annual Burden Hours: 3650 hours.

Total Annualized Burden for Record Keeping and Reporting: 3,770 Hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Cost to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION:

To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Joseph High, Head, Drug Management and Authorization Section, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division Cancer Therapy, Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 707, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number (301) 496–5725 or E-mail your request, including your address to: *JoeHigh@nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: June 30, 1997.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–18008 Filed 7–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Division of Extramural Activities; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel (Telephone Conference Call).

Date: July 23, 1997.

Time: 1:00 p.m.