ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Total Burden Hours	6	2	6	110	330

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

FDA based its estimates of the number of submissions expected in the future contained in the above table on the number of submissions submitted in the last 3 years and on the number of inquiries received indicating that applications would be submitted in the next year. FDA based its estimates of the time required to prepare submissions on discussions with those who have prepared submissions in the last 3 years. Persons are not required to respond to a collection of information unless it displays a valid control number.

Dated: November 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31321 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0266]

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

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 January 9, 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, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judy V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

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.

Surgical Instrument Marking Tape Survey

The mandate of FDA's Center for Devices and Radiological Health under the authority of sections 201–905 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321–395), and regulations contained in Title 21 of the Code of Federal Regulations includes the approval and adequate labeling of medical devices. Section 903(b)(2)(c) of the act (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to medical devices.

The regulatory status of adhesive-backed, colored tape on medical devices is under review by FDA. The tape is frequently applied to medical devices, particularly surgical instruments, to facilitate sorting. It may be considered an accessory to medical devices used in surgical treatment as defined by 21 CFR 878.4800.

There are two case reports in the literature in which adverse events are attributed to the use of adhesive-backed, colored tape to mark surgical instruments (*Journal of Oral Maxillofacial Surgery,* 41:687–688, 1983; and *British Journal of Surgery,* 74:696, 1987). Two additional adverse event reports have been submitted to FDA.

The purpose of the survey is to estimate the proportion of the population at risk from this practice, and to determine if use of operating room nurse managers as proxies for sampling health care facilities for this purpose is effective. In addition, data will be collected to identify tape durability, extent of use, and whether there are any practices or procedures for marking surgical instruments and/or any human factors that could be altered to better protect the public health. Labeling information will also be collected.

The proposed randomized survey will be a one-time data collection effort. Completion of the survey is voluntary, and anonymity of individuals and institutions will be protected. Survey results will be available to participants upon request.

The only respondent burden will derive from the time needed to respond to survey questions. This will occur on a one-time basis. The length of the screening portion (questions 1–7) is estimated at 5 minutes, and the full survey length is estimated at an additional 25 minutes. Burden estimates are based on the need to have 308 surveys returned to achieve a statistically significant sampling.

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

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Questions Only (30%)	92	1	92	0.083	7.63
Complete Survey (70%)	216	1	216	0.50	108
Total	308				115.63

There are no capital costs or operating and maintenance costs associated with this survey.

Dated: December 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31360 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0473]

Medirex, Inc.; Premarket Approval of the Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medirex, Inc., Wellesley Hills, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 9, 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: Russell P. Pagano, Center for Devices and Radiological Health (HFZ–472), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION: On September 29, 1993, Medirex, Inc., Wellesley Hills, MA 02181, submitted to CDRH an application for premarket approval of the Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact). These devices are indicated for use in the fragmentation of urinary tract stones (i.e., renal calyceal, renal pelvic, and upper ureteral stones).

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 (Pub. L. 101–629), this premarket approval application (PMA) was not referred to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 20, 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 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 January 9, 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–31359 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute; Notice of Meeting President's Cancer Panel

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the President's Cancer Panel.

This meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(9)(B), Title 5, U.S.C. for discussion and preparation of the Annual Report of the Chairman to the President for 1996. These discussions could disclose information, the premature disclosure of which would be likely to significantly frustrate implementation of proposed action the Panel may plan to take.

Carole Frank, Committee Management Specialist, National Cancer Institute, Executive Plaza North, Room 630, 9000 Rockville Pike, National Institutes of Health, Bethesda, Maryland 20892 (301–496–5708) will provide a roster of the committee members upon request.

Dr. Maureen O. Wilson, Executive Secretary, President's Cancer Panel, National Cancer Institute, Building 31, Room 4A48, National Institutes of Health, Bethesda, Maryland 20892 (301–496–1148) will provide a roster of the Panel members and substantive program information upon request.

Name of Committee: President's Cancer Panel.

Date: December 16, 1996.

Place: LaGuardia Marriott, 102–05 Ditmars Blvd., E. Elmhurst, New York 11369.

Closed: 9:30 am to 4 pm.

Agenda: Discussion of preparation of the mandatory Annual Report of the Chairman to the President.

Contact Person: Maureen O. Wilson, Ph.D., Executive Secretary, National Cancer Institute, NIH, Building 31, Room 4A48, 9000 Rockville Pike, Bethesda, MD 20892; (301) 496–1148.

This notice is being published less than 15 days prior to the meeting due to the urgent need to proceed with the meeting as scheduled to address this issue in a timely manner.

Dated: December 5, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–31369 Filed 12–9–96; 8:45 am]

BILLING CODE 4140–01–M