(2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Risk management programs are reviewed by divisions in the Center for Drug Evaluation and Research as part of the new drug application (NDA) review process as well as during the postmarketing period. In an effort to address safety risks associated with drug therapy, several risk management programs have been implemented (e.g., for clozapine, thalidomide, and bosentan). Many risk management programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures. Currently, the impact of risk management programs on the practice of pharmacy in terms of pharmacists' compliance, knowledge, burden, and barriers is not known.

The goal of this descriptive survey is to obtain information that will help FDA understand how risk management programs affect the practice of pharmacy and gain insight on practical interventions for future risk management programs. Findings from the survey will offer new insight and knowledge in risk management programs, and will enable FDA to make better decisions when reviewing new or existing risk management programs. Expected outcomes from the survey include a collection of data to evaluate pharmacists' knowledge of risk management programs, identify barriers of compliance, and assess the impact of these programs on the practice of pharmacy.

The descriptive survey will be sent to a representative sampling of pharmacists in the United States. Approximately 5,000 pharmacists will be chosen at random from listings of licensed pharmacists obtained from participating U.S. State Boards of Pharmacy. Because the number of licensed pharmacists in each State varies and the number of respondents from each State cannot be predicted, either a simple random or a stratified sample design will be used, depending on whether there is sufficient number of participating pharmacists to evaluate regional differences. The geographic regions would be classified by location in one of the four geographic regions of the United States corresponding to those used by the U.S. Bureau of Census (northeast, midwest, south, west).

The survey will be conducted via first-class mail. The survey will be mailed with a cover letter to randomly chosen pharmacists along with a preaddressed, stamped return envelope. To ensure anonymity and confidentiality, no premarkings or numbering systems will be recorded on the survey or return envelope.

From the sample size of approximately 5,000 pharmacists, the desirable response rate is approximately 75 to 85 percent. If needed, actions will be taken to increase the response rate, such as resending the survey approximately 2 weeks after the initial mailing.

FDA estimates that it will take each pharmacist approximately 20 minutes to respond to the survey and return it to FDA. The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

Number of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
5,000	1	5,000	.33	1,500

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

Dated: February 5, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–3433 Filed 2–11–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0296]

Agency Information Collection Activities; Announcement of OMB Approval; Investigational New Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Investigational New Drug Regulations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2002 (67 FR 64393, the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0014. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 5, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0645]

Medical Device Warning Letter Pilot Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Medical Device Warning Letter Pilot (MDWLP). This pilot concerns the issuance of warning letters for quality system, premarket notification (510(k)), and labeling violations. The intent is to inform the