recommendations will be accepted from the public if received by the individuals designated below by February 19, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* Targeted Beneficiary Survey on Access to Physician Services Among Medicare Beneficiaries; *Form No.:* CMS–10084 (OMB# 0938–NEW); *Use:* Recent anecdotal reports have suggested that Medicare beneficiaries in certain parts of the country are having difficulty finding physicians who will accept new Medicare patients. In response to these anecdotes, CMS implemented a multi-faceted monitoring system that incorporated multiple data sources to address beneficiaries' reported access problems. As part of this monitoring strategy, CMS has designed a Targeted Survey on Access to Physician Services Among Medicare Beneficiaries. The survey is designed to interview 300 Medicare beneficiaries in each of 11 geographic areas where there is some evidence to suggest a potential physician access problem. The geographic areas include the state of Alaska; the Phoenix, Arizona area; the San Diego, California and San Francisco, California areas; the Denver, Colorado area; the Tampa, Florida area; the Springfield, Missouri area; the Las Vegas, Nevada area; the Brooklyn, New York area; the Fort Worth, Texas area; and the Seattle, Washington area. Survey respondents will be Medicare beneficiaries in the traditional Medicare program who are covered by part B where Medicare is the primary payer. The survey will over sample beneficiaries who are most likely to be seeking new physicians. The goal of the survey is to confirm or refute anecdotal reports that the Medicare payment restrictions are contributing to physician access problems. The survey will inform CMS about the characteristics of Medicare beneficiaries most likely to be experiencing physician access problems. It will enhance CMS's ability to consider the potential effects of payment changes on beneficiary access. *Frequency:* One-time; *Affected Public:* Individuals or households; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 958.

We have submitted a copy of this notice to OMB for its review of these information collections.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by February 19, 2003:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, CMS–10084, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167. Attn: Brenda Agular, CMS Desk Officer.

Dated: February 4, 2003.

Anthony Mazzarella,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–3447 Filed 2–11–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0017]

Agency Information Collection Activities; Proposed Collection; Comment Request; Impact of Risk Management Programs on the Practice of Pharmacy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to conduct a descriptive survey of pharmacists to evaluate pharmacists' knowledge of risk management programs, identify barriers to compliance, and assess the impact of these programs on the practice of pharmacy.

DATES: Submit written or electronic comments on the collection of information by April 14, 2003.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(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]

BILLING CODE 4160–01–S

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.

[FR Doc. 03–3435 Filed 2–11–03; 8:45 am]

BILLING CODE 4160–01–S

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