those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Nonfederal Resources

Description: Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF–424.

Justification: The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

Dated: July 8, 2003.

Howard Rolston,

Director, Office of Planning, Research, and Evaluation, Administration for Children and Families.

[FR Doc. 03–17605 Filed 7–10–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0017]

Agency Information Collection Activities; Submission for OMB Review; 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 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: Fax written comments on the collection of information by August 11, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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

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

Impact of Risk Management Programs on the Practice of Pharmacy

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the survey entitled ''Impact of Risk Management Programs on the Practice of Pharmacy.''

Risk management (RM) programs are reviewed by divisions in the Center for Drug Evaluation and Research (CDER) 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 RM programs have been implemented (for example, for clozapine, thalidomide, and bosentan). Many RM programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures. Currently, the impact of RM programs on the practice of pharmacy in terms of pharmacists' compliance, knowledge, burden, and barriers is not known.

The survey is a small investigator-initiated research project to improve science safety review within CDER. The research is intended to help FDA safety evaluators of drug adverse events understand the larger context of RM programs and how they are perceived and implemented by pharmacists. The study is independent from the Prescription Drug User Fee Act III guidance that is currently under development on RM.

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 a sufficient number of participating pharmacists to evaluate regional differences. The geographic regions will 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, and 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.

In the **Federal Register** of February 12, 2003 (68 FR 7124), FDA published a notice requesting comments on FDA's burden estimates to conduct a descriptive survey of pharmacists to evaluate pharmacists' knowledge of RM programs, identify barriers to compliance, and assess the impact of these programs on the practice of pharmacy. FDA received one comment. A summary of the comment and FDA's responses are in the following paragraphs.

Concerning the issue of sampling methodology, the comment said that the primary focus of the survey should be on community pharmacists who are most likely to dispense medications associated with RM programs.

FDA believes that RM programs may affect pharmacists in all practice settings; during drug dispensing, answering drug information questions, and/or monitoring drug therapy. For this reason, the primary focus of the survey is not on community pharmacists. However, FDA will analyze responses according to pharmacy practice settings (for example, retail, hospital, and long-term care).

The comment said that the sampling frame should be stratified to obtain an equal distribution of pharmacists working in chain versus independent pharmacies.

FDA notes that the primary objective of the survey is not to compare the responses between chain and independent pharmacies. In addition, because the sampling frame does not include the setting information in which the pharmacist works, the agency cannot stratify the sampling frame. However, the survey contains a question regarding the practice setting of surveyed pharmacists and FDA intends to analyze this data.

The comment said that the survey should be accompanied by an explanation or incentive that provides a compelling reason for a pharmacist to complete it.

FDA believes that the cover letter that will accompany the survey will accomplish this suggestion because the cover letter will explain what the survey is about and that it is intended to gain insight from a pharmacist's point of view. The comment said that the sampling size should be reduced.

The survey's sample size was selected by FDA based on a consideration of response rate and cost. FDA is also concerned about the possibility that a large number of pharmacists in the sample may not have encountered RM programs. The agency believes that in a sample size of 5,000, sufficient responses may be received to gain some insight about pharmacists' experiences in dispensing drugs.

Concerning the enhancement of response rates, the comment said that a cover letter explaining why it is important for selected respondents to participate would result in a greater likelihood that sample pharmacists will participate. The letter should include an offer to send a report of the results directly to the respondent and assurance that the responses will be kept confidential.

FDA notes that a cover letter will be included with the survey explaining why the selected respondents should participate. The letter will state that the surveys are not marked and that the respondents are not identifiable. FDA intends to post the results of the survey on FDA's Web site at: *www.fda.gov.*

The comment suggested that disclosures be included on the outside envelope that will make the survey mailing ''stand out'' from the clutter of other mailings.

FDA intends to include FDA's logo on the outside envelope along with a stamped message (for example, ''Important'').

The comment said that a more comprehensive followup plan would result in greater participation.

FDA plans to send two mailings of the same survey to the selected pharmacists. A reminder postcard will be sent between these two mailings to inform the pharmacists that the second mailing will be arriving soon. The reminder postcard will also state that if the survey has already been completed and returned to FDA, the second mailing should be disregarded.

Concerning the enhancement of the quality, utility, and clarity of the information, the comment said that the survey should be revised to include questions about what educational programs might be helpful in facilitating compliance with RM programs.

FDA agrees that educating patients and health care professionals about drug risks is an important component of RM programs. The survey contains questions about existing communication tools (for example, medication guides, dear health professional letters, drug educational material), barriers to compliance, and the ways to improve this communication.

The comment said that question number 20 of the survey should be revised to measure barriers to compliance through the inclusion of: (1) A new section heading and introductory sentence or two to clarify the scope of the queries, and (2) a change to the format that would allow indication of the severity of the problem.

FDA has added self-explanatory section headings to the survey. Because the agency would consider the identification of any barrier to compliance significant, categorizing the severity of the problem would be unnecessary.

The comment said that the survey should include questions that examine the impact on the practice of pharmacy of any of the three different RM components examined (use of special prescription stickers, dear health care professional/pharmacist letters, labeling/patient information/medication guides), because this is the stated goal of the research.

FDA has added a question to the survey specifically addressing the impact of RM programs on the practice of pharmacy. In addition, the format of the question is open-ended so that the response would not be restricted in any way.

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: July 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17574 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ivermectin Pour-On

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2001 it approved a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provided for topical use of an ivermectin solution on cattle for control of certain internal parasites for 14 days after treatment. The applicable section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2001 it approved a supplemental ANADA that was not the subject of a final rule. A final rule was not published because § 524.1193 (21 CFR 524.1193) did not require amendment.

On May 16, 2001, FDA approved a supplement filed by Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, to ANADA 200–219 for PHOENECTIN (ivermectin) Pour-On. The supplemental ANADA provided for topical use of a 0.5 percent ivermectin solution on cattle for control of infections of *Ostertagia ostertagi*,