

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 BURDEN¹

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*,