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*,

Haemonchus placei, *Trichostrongylus axei*, *Oesophagostomum radiatum*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment. This supplemental approval was based on the expiration of marketing exclusivity granted the pioneer product, Merial, Ltd.'s IVOMEC Pour-On for Cattle, in 1997 (62 FR 38907, July 21, 1997). No new data were submitted. The necessary amendment to § 524.1193 was made in a final rule (66 FR 13236, March 5, 2001) for the approval of another generic copy of the pioneer product.

A freedom of information summary containing approved product labeling may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–17638 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0233]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Amiloxate (isoamyl p-methoxycinnamate), up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; enzacamene (methyl benzylidene camphor), up to 4 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; and octyl triazone, up to 5 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients. FDA has reviewed time and extent applications (TEAs) for these conditions and determined that they are eligible for consideration in it's OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

DATES: Submit data, information, and general comments by October 9, 2003.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEAs that the agency reviewed (Refs. 1, 2, and 3) and FDA's evaluation of the TEAs (Refs. 4, 5, and 6) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document.

II. Request for Data and Information

The conditions amiloxate, up to 10 percent; enzacamene, up to 4 percent; and octyl triazone, up to 5 percent, as sunscreen single active ingredients and in combination with other existing monograph sunscreen active ingredients will be evaluated for inclusion in the monograph for OTC sunscreen drug products (21 CFR part 352). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of these single active ingredients for FDA to determine whether they can be GRAS/E and not misbranded under recommended conditions of OTC use. Additional data (from human clinical studies) should be included to establish the safety and effectiveness of combination sunscreen drug products containing amiloxate, enzacamene, or octyl triazone with other existing sunscreen monograph active ingredients.

Interested persons should submit comments, data, and information to the Divison of Dockets Management (see **ADDRESSES**) by October 9, 2003. Three copies of all comments, data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under § 10.30 (21 CFR 10.30).

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for amiloxate (isoamyl p-methoxycinnamate) submitted by Haarmann & Reimer Corp. dated August 14, 2002.

2. TEA for enzacamene (methyl benzylidene camphor) submitted by