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

Buchanan Ingersoll on behalf of Merck KGaA dated August 21, 2002.

3. TEA for octyl triazone submitted by Morgan, Lewis & Bockius LLP on behalf of BASF AG dated August 21, 2002.

4. FDA's evaluation and comments on the TEA for amiloxate.

5. FDA's evaluation and comments on the TEA for enzacamene.

6. FDA's evaluation and comments on the TEA for octyl triazone.

Dated: July 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17637 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–0069]

Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Food and Human Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report of its Task Force on Consumer Health Information for Better Nutrition (the Task force) and two final guidance documents entitled ''Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data'' and ''Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.'' These documents further update the agency's approach on how it intends to implement the Court of Appeals decision in *Pearson* v. *Shalala*. FDA is taking this action to inform interested persons of the release of the Task Force report and to make available the guidances announced in the Task Force report in accordance with FDA's good guidance practices.

DATES: The guidances are final on July 11, 2003. However, you may submit written or electronic comments on the guidances at any time.

ADDRESSES: Submit written requests for single copies of the Task Force report and the final guidances to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Task Force report and the final guidances.

Submit written comments on the final guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please identify whether you are commenting on one or both of the guidances when you submit your written comments. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Kathleen Ellwood, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional human food and human dietary supplements to help American consumers improve their health and prevent diseases by making sound dietary decisions. This initiative has as its central focus improving the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. FDA announced on January 16, 2003, that one element of this initiative was to set up an FDA Task Force and to issue a report of that Task Force approximately 6 months after the initiative was launched. The Task Force includes representatives from FDA, the Federal Trade Commission (FTC), and the National Institutes of Health.

The Task Force was charged with: (1) Reporting on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should evaluate scientific evidence for qualified health claims in order to achieve these goals; (2) developing a framework of regulations that will give these principles the force and the effect of law; (3) identifying procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of qualified health claim petitions; and (4) developing a consumer studies research agenda designed to identify the most effective ways to present scientifically-based, truthful and nonmisleading information to consumers and to identify the kinds of information known to be misleading to consumers.

On March 13, 2003, the Task Force established a public docket (docket number 2003N–0069) to receive views and comments from interested stakeholders. As part of FDA's continued commitment to ensure that stakeholders remain fully informed of our progress as we implement this initiative, FDA is making available the Task Force report, which includes nine attachments (Attachments A through I). Refer to section II of this document for a brief description of the attachments. The Task Force report entitled ''Consumer Health Information for Better Nutrition Initiative—Task Force Report—July 2003'' is available on FDA's Web sites at *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm* and by requesting paper copies from the contact person (see **FOR FURTHER INFORMATION CONTACT**). The final guidances are available at *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm.*

II. Task Force Report

The Task Force report includes a transmittal memorandum from the Chair and Vice Chair of the Task Force to the Commissioner of Food and Drugs, an executive summary, and the following attachments:

A. Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

This attachment describes three options or alternatives for regulating health claims that do not meet the ''significant scientific agreement'' standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims.

B. Guidance: Interim Evidence-Based Ranking System for Scientific Data

This interim evidence-based ranking system describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a petition for a qualified health claim. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease