(section 301(j) of the Federal Food, Drug, and Cosmetic Act) was deleted from the TEA before it was placed on public display.

II. Request for Comments, Data, and Information

FDA has determined that the information submitted in this TEA satisfies the criteria of § 330.14(b). FDA will evaluate both leave-on formulations containing 0.2 to 0.5 percent triclosan and rinse-off formulations containing 0.3 to 1.0 percent triclosan for inclusion in the monograph for OTC topical acne drug products (21 CFR part 333, subpart D). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for this use, so that FDA can determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments, data, and information. Submit three copies of all comments, data, and information. 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 21 CFR 10.30.

III. Marketing Policy

Under § 330.14(h), any product containing the conditions 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. Amended TEA for triclosan as an acne active ingredient submitted by CIBA Specialty Chemicals Corp., on April 22, 2004.

2. FDA's evaluation and comments on the TEA for triclosan.

Dated: November 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23570 Filed 12–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0444]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient

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: Climbazole, 0.1 to 0.5 percent and 0.5 to 2.0 percent, as a dandruff control active ingredient in leave-on and rinse-off dosage forms, respectively. FDA has reviewed a time and extent application (TEA) for these conditions and determined that they are eligible for consideration in its 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 (GRASE) for their proposed OTC use.

DATES: Submit data, information, and general comments by March 6, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0444, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments, Data, and Information'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (mail stop 5411), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, Silver Spring, MD 20993, 301–796–2090.

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 TEA that FDA reviewed (Ref. 1) and the FDA's evaluation of the TEA (Ref. 2) 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. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) (section 301(j) of the Federal Food, Drug, and Cosmetic Act) was deleted from the TEA before it was placed on public display.

II. Request for Comments, Data, and Information

FDA has determined that the information submitted in this TEA satisfies the criteria of § 330.14(b). FDA will evaluate both leave-on formulations containing 0.1 to 0.5 percent climbazole and rinse-off formulations containing 0.5 to 2.0 percent climbazole for inclusion in the monograph for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis (21 CFR part 358, subpart H). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for this use, so that FDA can determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use. The TEA did not include an official or proposed United States Pharmacopeia-National Formulary (USP–NF) drug monograph for climbazole. According to § 330.14(i), an official or proposed USP–NF monograph for climbazole must be included as part of the safety and effectiveness data for this ingredient. Interested parties should provide an official or proposed USP–NF monograph.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments, data, and information. Submit three copies of all comments, data, and information. 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 21 CFR 10.30.

III. Marketing Policy

Under § 330.14(h), any product containing the conditions 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 climbazole as a dandruff control active ingredient submitted by Steinberg & Associates on behalf of Symrise, Inc., on December 15, 2004.

2. FDA's evaluation and comments on the TEA for climbazole.

Dated: November 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23569 Filed 12–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0446]

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: Bisoctrizole, up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; and bemotrizinol, up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients. FDA reviewed time and extent applications (TEAs) for these conditions and determined that they are eligible for consideration in our 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 March 6, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0446, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments, Data and Information'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug