

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2004N-0346]

**Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Antidiarrheal Ingredient**

**AGENCY:** Food and Drug Administration, HHS.

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

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products:

*Saccharomyces boulardii* (*S. boulardii*), 250 milligrams (mg) ( $4.5 \times 10^9$  lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg ( $9.0 \times 10^9$  yeast cells), in capsule form as an antidiarrheal ingredient. FDA has reviewed a time and extent application (TEA) for this condition and determined that it is eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether this condition can be generally recognized as safe and effective (GRAS/E) for its proposed OTC use.

**DATES:** Submit data, information, and general comments by [*insert date 90 days after date of publication in the Federal Register*].

**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:** Michael L. Koenig, 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 TEA that FDA reviewed (Ref. 1) and 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) was deleted from the TEA before it was placed on public display.

## **II. Request for Data and Information**

FDA intends to evaluate the condition *S. boulardii*, 250 mg ( $4.5 \times 10^9$  lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg ( $9.0 \times 10^9$  yeast cells), in capsule form for inclusion in the monograph for OTC antidiarrheal drug products (21 CFR part 335).

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 FDA to 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 *S. boulardii*. According to § 330.14(i), an official or proposed USP–NF monograph for *S. boulardii* 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 for evaluation by FDA.

Interested persons should submit comments, data, and information to the Division of Dockets Management. 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 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 and addendum for *S. boulardii* as an antidiarrheal active ingredient submitted by Parexel.

2. FDA's evaluation and comments on the TEA for *S. boulardii*.

Dated: 8/11/04  
August 11, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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