collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–19256 Filed 8–20–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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.

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) (4.5×10^9 lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg (9.0×10^9 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 November 22, 2004.

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 (4.5×10^9 lyophilized, viable yeast cells) taken 1 to 2 times daily with a maximum daily dose of 500 mg (9.0×10^9 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: August 11, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19180 Filed 8–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0330]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the PediatricAdvisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of August 4, 2004 (69 FR 47157). The amendment is being made to reflect changes in the *Addresses* and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *patelA@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 4, 2004, FDA announced that a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee would be held on September 13 and 14, 2004. On page 47157, in the third column, the *Addresses* and on page 47158, in the second column, the *Procedure* portions are amended to read as follows:

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select ''2004N–0330—Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments received by August 23, 2004, will be provided to the committee before the meeting. Comments received after August 23, 2004, will be reviewed by FDA's decision makers.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the Division of Dockets Management as stated in the *Addresses* section of this document. Oral presentations from the public will be scheduled between approximately 2 p.m. to 6 p.m. on September 13, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before 4:30 p.m. on August 27, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Docket ''2004N–0330—Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients'' will remain open for public submissions until July 29, 2005.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR Part 14, relating to advisory committees.

Dated: August 13, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning..

[FR Doc. 04–19224 Filed 8–18–04; 12:34 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0352]

Global Harmonization Task Force, Study Groups 1 and 2; New Proposed Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two proposed documents that have been prepared by Study Groups 1 and 2 of the Global Harmonization Task Force (GHTF). These documents are intended to provide information only and represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments on any of the documents by November 22, 2004. After the close of the comment period, written comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written comments on the documents to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the Internet, submit written requests for single copies on a 3.5″ diskette of the document to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. See the **ELECTRONIC ACCESS** section for information on electronic access to these documents.

FOR FURTHER INFORMATION CONTACT:

For Study Group 1: Ginette Michaud, GHTF, Study Group 1, Office of In Vitro Diagnostic Devices (HFZ–440), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, ext. 157;

For Study Group 2: Stephen Sykes, GHTF, Study Group 2, Office of Surveillance and Biometrics (HFZ–500), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3673.

SUPPLEMENTARY INFORMATION: