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: