Ave., Bldg. 22, rm. 5122, Silver Spring, MD 20993–0002, 301–796–0910.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Irritable Bowel Syndrome—Clinical Evaluation of Products for Treatment." This guidance is intended to assist the pharmaceutical industry and other investigators who are conducting new product development for the treatment of IBS–D and IBS–C.

A content-valid PRO instrument that measures the clinically important signs and symptoms associated with each IBS subtype is the ideal primary efficacy assessment tool in clinical trials used to support labeling claims. However, at this time, an adequate instrument is not available. We recognize that it will take some time to develop adequate instruments and that in the meantime there is a great need to develop effective therapies for patients with IBS. Therefore, until the appropriate PRO instruments have been developed, this guidance recommends interim strategies for IBS clinical trial design and endpoints, and discusses the future development of PRO instruments for use in IBS clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on clinical evaluation of products for the treatment of irritable bowel syndrome. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6310 Filed 3–22–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Food and Drug Administration and Process Analytical Technology for Pharma Manufacturing: Food and Drug Administration—Partnering With Industry; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) is announcing a joint conference with the University of Rhode Island (URI) College of Pharmacy entitled "FDA and PAT for Pharma Manufacturing: FDA—Partnering with Industry." This 2-day public conference is cosponsored by FDA and the URI College of Pharmacy. This public conference is intended to disseminate current and accurate information on process analytical technology (PAT) to the pharmaceutical industry and create a venue for dialogue between PAT users and FDA. The public conference will feature FDA's perspective on where PAT will be applicable in the manufacturing process and FDA's current thinking on how PAT will be reviewed in new and abbreviated new drug applications, amendments, or supplements to an application.

Date and time: The public conference will be held on May 11 and 12, 2010, from 8 a.m. to 5 p.m.

Location: The public conference will be held at the Hyatt Regency Bethesda, One Bethesda Metro, Bethesda, MD 20814, 301–657–1234.

Contact Persons:

For information regarding the conference and registration: Christi Counts, Pharma Conference Inc., P.O. Box 291386, Kerrville, TX, 78029–1386, 830–896–0027, FAX: 830–896–0029, *http://www.pharmaconference.com*.

For information regarding this notice: Chris Watts, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4142, Silver Spring, MD 20993–0002, 301–796–1625.

Registration: There is a registration fee. The registration fee includes conference materials, continental breakfast, breaks, and lunches. For payment received by April 15, 2010, the fee is $1,795. For payment received after April 15, 2010, the fee is $1,995. The fee for government employees is $750. The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks. No checks will be accepted on site. Early registration is recommended because seating is limited. There will be no onsite registration. To register for the public conference online, please visit *http://www.pharmaconference.com/upcoming2010/beth_10.htm*. To register by mail, please send your name, title, firm name, address, telephone and fax numbers, e-mail, and credit card information or a company check for the fee to Pharma Conference Inc., P.O. Box 291386, Kerrville, TX, 78029–1386. To register by overnight mail, the address is Pharma Conference Inc., 819 Water St., suite 350, Kerrville, TX, 78028.

If you need special accommodations due to a disability, please notify Pharma Conference Inc., once you receive your registration confirmation so these needs can be passed on to the conference venue.

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6265 Filed 3–22–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0201] (formerly Docket No. 2007D–0118)

Guidance for Industry on the Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format." This guidance is one of a series of guidance documents intended to assist applicants in drafting prescription drug labeling in which prescribing information is clear and accessible and in complying with the requirements in the final rule on the content and format of labeling for