

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FDA is announcing the availability of a draft guidance for industry entitled "Irritable Bowel Syndrome—Clinical Evaluation of Products for Treatment."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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on clinical evaluation of products for the treatment of irritable bowel syndrome.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/>

[www.regulations.gov/Guidances/default.htm](http://www.regulations.gov/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](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

prescription drug and biological products. This guidance is intended to help applicants select information for inclusion in the "Dosage and Administration" section of labeling and to help them organize that information.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Joseph P. Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993-0002, 301-796-2270; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

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." The guidance provides recommendations on how to select information for inclusion in the "Dosage and Administration" section of labeling and how to organize information within the section. This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the format and content of certain sections of the labeling for prescription drugs. In the **Federal Register** of January

24, 2006 (71 FR 3998), FDA issued final guidances on the format and content of the "Adverse Reactions" and "Clinical Studies" sections of labeling and draft guidances on implementing the new labeling requirements for prescription drugs and the format and content of the "Warnings and Precautions," "Contraindications," and "Boxed Warning" sections of labeling. In the **Federal Register** of March 3, 2009 (74 FR 9250), FDA issued a draft guidance on the format and content of the "Clinical Pharmacology" section of labeling. The labeling requirements (71 FR 3922) and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

On April 9, 2007, FDA issued a draft of this guidance on the dosage and administration section of labeling to obtain public comment (72 FR 17561). FDA received 10 comments—9 from the pharmaceutical industry (individual companies, a trade association, and a consultant) and 1 from an academic medical center. The comments offered generally favorable impressions of the guidance and its goals. The bulk of the comments focused on clarifications and further illustrations of issues discussed in individual sections and subsections of the guidance. FDA made an effort to address as many of the identified concerns as possible. A recurring general concern in many industry comments was that the guidance should more clearly differentiate content that is required when relevant to a given drug from content that is recommended. FDA has attempted to make the distinction as clear as possible by using the word "must" and citing the relevant section of the regulation whenever the guidance is discussing required content and using the word "should" when discussing recommended content.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the content and format of the "Dosage and Administration" section of labeling for human prescription drug and biological products. 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. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910-0572.

##### **IV. Electronic Access**

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

Dated: March 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-6322 Filed 3-22-10; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small