delivering the survey has not been established. FDA will take into consideration NACCHO's suggestion of developing a Web-based portal with log in capability to allow multiple users to log in to the same survey to increase the efficiency of completing the survey. In addition, hardcopies of the survey can be made available upon request.

(Comment 6) The assessment should be conducted on a routine basis.

(Response) FDA agrees with NACCHO in its statement that a survey, such as this one, should be conducted on a more regular basis to track and trend gaps. At this time, this survey is intended to be a one-time collection of information. FDA could consider conducting future surveys, depending on Agency resources and priorities.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Current State and local government agencies	1,400	1	1,400	1	1,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This survey isslated to be a one-time survey. Through testing on six FDA employees who were former State employees, the survey development team has concluded that it should take no longer than 1 hour for the 1,400 current State and local government agencies to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13140 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0146]

Guidance for Industry on Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment; 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 ''Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment.'' This guidance is intended to assist the pharmaceutical industry and investigators who are developing drugs for the treatment of irritable bowel syndrome (IBS), specifically the IBS indications for IBS with diarrhea (IBS–D) and IBS with constipation (IBS–C). The guidance describes the evolution of patient-reported outcome (PRO) measures as primary endpoints for IBS clinical trials, and sets forth provisional endpoints and trial design recommendations that sponsors may apply to IBS clinical trials as PRO measurements continue to evolve. The guidance also discusses the future development of IBS PRO instruments. This guidance finalizes the draft guidance published in March 2010.

DATES: Submit either electronic or written 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ruyi He, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–0910.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment.'' This guidance is intended to assist the pharmaceutical industry and investigators who are developing drugs for the treatment of IBS. This guidance applies to the IBS indications for IBS–D and IBS–C.

A well-defined and reliable PRO instrument that measures the clinically important signs and symptoms associated with each IBS subtype would be the ideal primary efficacy assessment tool in clinical trials used to support labeling claims, but at this time such an 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, sponsors should consider the provisional endpoints and trial design recommendations set forth in the guidance.

This guidance was published as a draft guidance in March 2010. Changes made to the guidance took into consideration written and verbal comments received. In addition to editorial changes primarily for clarification, the major changes are as follows:

- The section on trial design was modified by adding a randomized withdrawal design to address the need for maintenance treatment to prevent sign or symptom recurrence.
- The section on trial endpoints was modified to note that a drug can be specifically developed to treat only one of two major signs or symptoms of IBS (abnormal defecation or abdominal pain). Demonstration of significant and clinically meaningful changes in the targeted single endpoint could serve as a basis for approval, as long as the other important symptom or sign has not worsened on treatment.
- Trial entry criteria for IBS–D were modified to allow more IBS–D patients to participate in IBS clinical trials, and the definition of a responder to treatments for IBS–D was modified accordingly.
- Definitions of a responder for abdominal pain alone, constipation, and diarrhea were added.

• The use of a daily responder analysis for IBS–D as a primary analysis was included.

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 clinical evaluation of drugs for the treatment of IBS. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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: May 23, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13143 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory 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 meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of March 30, 2012 (77 FR 19293). The amendment is being made to reflect a change in the **DATES** and **ADDRESSES** portion of the document. The amendment also provides a Web address where the meeting webcast can be accessed. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–3805, *Avena.Russell@fda.hhs.gov,* or please use the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 30, 2012, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel would be held on June 27 and 28, 2012. On page 19293, in the first column the **DATES** portion of the document is changed to read as follows:

The meeting will be held on June 27 and 28, 2012, from 7:30 a.m. to 7 p.m. On page 19293, in the first column, the **ADDRESSES** portion of the document is changed to read as follows:

Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

The meeting will be webcast live and free of charge on both days and can be accessed at the following Web address:

On June 27, Day 1

http://fda.yorkcast.com/webcast/Viewer/?peid=12f84ea095b445d78e9b115f495392731d

On June 28, Day 2

http://fda.yorkcast.com/webcast/Viewer/?peid=901726ab91944b158ac705e48664921c1d

The webcast will be broadcast using Windows Media Player.

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

Dated: May 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–13157 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 24, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/Advisory*