

conducted or supported by HHS. The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57487). OHRP received comments on the draft guidance document from 18 individuals and organizations, and those comments were considered as the guidance was finalized.

**DATES:** Comments on OHRP guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for a single copy of the guidance document entitled, "Guidance on IRB Continuing Review of Research," to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-402-2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit written comments to Comments on Continuing Review Guidance, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to [ohrp@hhs.gov](mailto:ohrp@hhs.gov) or via facsimile at 240-402-2071.

**FOR FURTHER INFORMATION CONTACT:** Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail [Irene.Stith-Coleman@hhs.gov](mailto:Irene.Stith-Coleman@hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

OHRP is announcing the availability of a guidance document entitled "Guidance on IRB Continuing Review of Research." The guidance document supersedes OHRP's January 15, 2007 guidance entitled "Guidance on Continuing Review." The document is intended primarily for IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS.

The guidance document applies to non-exempt human subjects research conducted or supported by HHS. It provides guidance on the authority of IRBs to approve research with conditions. In particular, the guidance addresses the following 11 topics:

(1) Key IRB Considerations When Evaluating Research Undergoing Continuing Review;

(2) Process for Conducting Continuing Review;

(3) Additional Considerations for Continuing Review of Multicenter Research Projects;

(4) When Expedited Review Procedures may be Used by an IRB for Continuing Review;

(5) Determining the Frequency of Continuing Review;

(6) Determining the Effective Date of Initial IRB Approval and the Dates for Continuing Review;

(7) Lapses in IRB Approval;

(8) Communicating the IRB's Continuing Review Determination to Investigators and the Institution;

(9) Suspension or Termination of IRB Approval of Research or Disapproval of Research at the Time of Continuing Review;

(10) Identifying the Point When Continuing Review is no Longer Necessary; and

(11) Continuing Review is Not Required for Exempt Human Subjects Research Projects.

The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57487). OHRP received comments on the draft guidance document from 18 individuals and organizations, and those comments were considered as the guidance was finalized. The majority of commenters expressed general support for the draft guidance document. The final guidance document is largely unchanged from what was proposed in the draft guidance, with only minor clarifying edits made in response to many of the comments.

To enhance human subject protections and reduce regulatory burden, OHRP and the Food and Drug Administration (FDA) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. The guidance document announced in this notice was developed as a part of these efforts. When FDA finalizes its related guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval," which was made available in draft for public comment through a notice in the **Federal Register** on January 13, 2010 (75 FR 1790), OHRP will update the guidance document announced in this notice as needed to harmonize with FDA's final guidance document.

**II. Electronic Access**

The guidance document is available on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/continuingreview2010.html> or <http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf>.

**III. Comments**

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

Dated: November 24, 2010.

**Jerry Menikoff,**

*Director, Office for Human Research Protections.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0001]

**Food 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:* Food 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 March 30 and 31, 2011, from 8:30 a.m. to 4:30 p.m.

*Location:* The Hilton Hotel, Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200.

*Contact Person:* Carolyn Jeletic, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1913 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014510564. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The Food Advisory Committee will meet to discuss whether available relevant data demonstrate a link between children's consumption of synthetic color additives in food and adverse effects on behavior.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**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 contact person on or before March 23, 2011. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. on March 31, 2011. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before March 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 16, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carolyn

Jeletic at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 24, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-30187 Filed 11-30-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Food Labeling Workshop; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with Iowa State University, is announcing a public workshop entitled "Food Labeling Workshop." This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

**Date and Time:** This public workshop will be held on March 3 and 4, 2011, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Scheman Conference Center, Lincoln Way and University Avenue, Iowa State Center, Ames, IA.

**Contact:** David Arvelo, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or email: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

For information on accommodation options, visit <http://www.fshn.hs.iastate.edu/foodlabel/register.php> or contact Dr. Ruth MacDonald, 2312 Food Sciences Building, Iowa State University, Ames, IA 50011, 515-294-5991, FAX: 515-294-8181, email: [ruthmacd@iastate.edu](mailto:ruthmacd@iastate.edu).

**Registration:** You are encouraged to register by February 21, 2011. The workshop has a \$250 registration fee to cover the cost of facilities, materials, lunch on day 1, and breaks. There is no registration fee for FDA employees. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$350 payable to: "Iowa State University." If you need special accommodations due to a disability, please contact Dr. Ruth MacDonald (*see Contact*) at least 14 days in advance.

**Registration Form Instructions:** To register, please complete the online registration form at <http://www.fshn.hs.iastate.edu/foodlabel/register.php>, or submit your full name, business or organization name, complete mailing address, telephone number, email address, optional fax number, and any special accommodations required due to disability, along with a check or money order for \$250 payable to "Iowa State University." Mail to: Dr. Ruth MacDonald, Food Science and Human Nutrition, 2312 Food Sciences Building, Ames, IA 50011.

**Transcripts:** Transcripts of the public workshop will not be available due to the format of this workshop. Requests for workshop handouts may be obtained through David Arvelo (*see Contact*).

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by FDA's Kansas City District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the SBR Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is