

of information in sections 1–2 of this guidance have been approved under OMB Control No. 0910–0032.

IV. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "require," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 applicable statutes and regulations.

V. 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.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: July 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Risk Communication 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: Risk Communication 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 August 13, 2009, from 8 a.m. to 5 p.m. and August 14, 2009, from 8 a.m. to 2 p.m.

Location: National Transportation Safety Board (NTSB) Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594 (at Metro's L'Enfant Plaza station; parking is limited and public transportation is recommended.)

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning, Food and Drug Administration, 5600 Fishers Lane, rm. 14–90, Rockville, MD 20857, 301–827–2895, FAX: 301–827–4050, e-mail: RCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. 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: On August 13 and 14, 2009, the Committee will discuss FDA's external research on, and internal assessment of, communications about food safety problems. This discussion will address research on consumer knowledge of food recalls and plans for how to monitor communication effectiveness during the course of a recall. The purpose of the discussion is to advise FDA on developing more effective communication strategies. Also on August 14, 2009, the RCAC will be briefed on the work of the FDA Transparency Task Force.

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>, click on the year 2009 and 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 August 7, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 13th and 10:30 to 11:30 a.m. on August 14th. Those desiring to make 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 August 6, 2009. 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 August 7, 2009.

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 Lee L. Zwanziger 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.

Dated: July 10, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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