

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0042]

ADM

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**Draft Guidance on the Open Public Hearing; Food and Drug Administration
Advisory Committee Meetings; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled “The Open Public Hearing; FDA Advisory Committee Meetings.” This draft guidance is for members of the public who choose to participate in the open public hearing (OPH) session of an FDA advisory committee meeting. The draft guidance is intended to answer more fully questions about how the public may participate at an OPH session, and it includes topics such as meeting logistics and administrative requirements.

DATES: Submit written or electronic comments on this draft guidance by *[insert date 120 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Linda Ann Sherman, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Linda Ann Sherman, Office of the Commissioner (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220, e-mail: disclosure@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled “The Open Public Hearing; FDA Advisory Committee Meetings.”

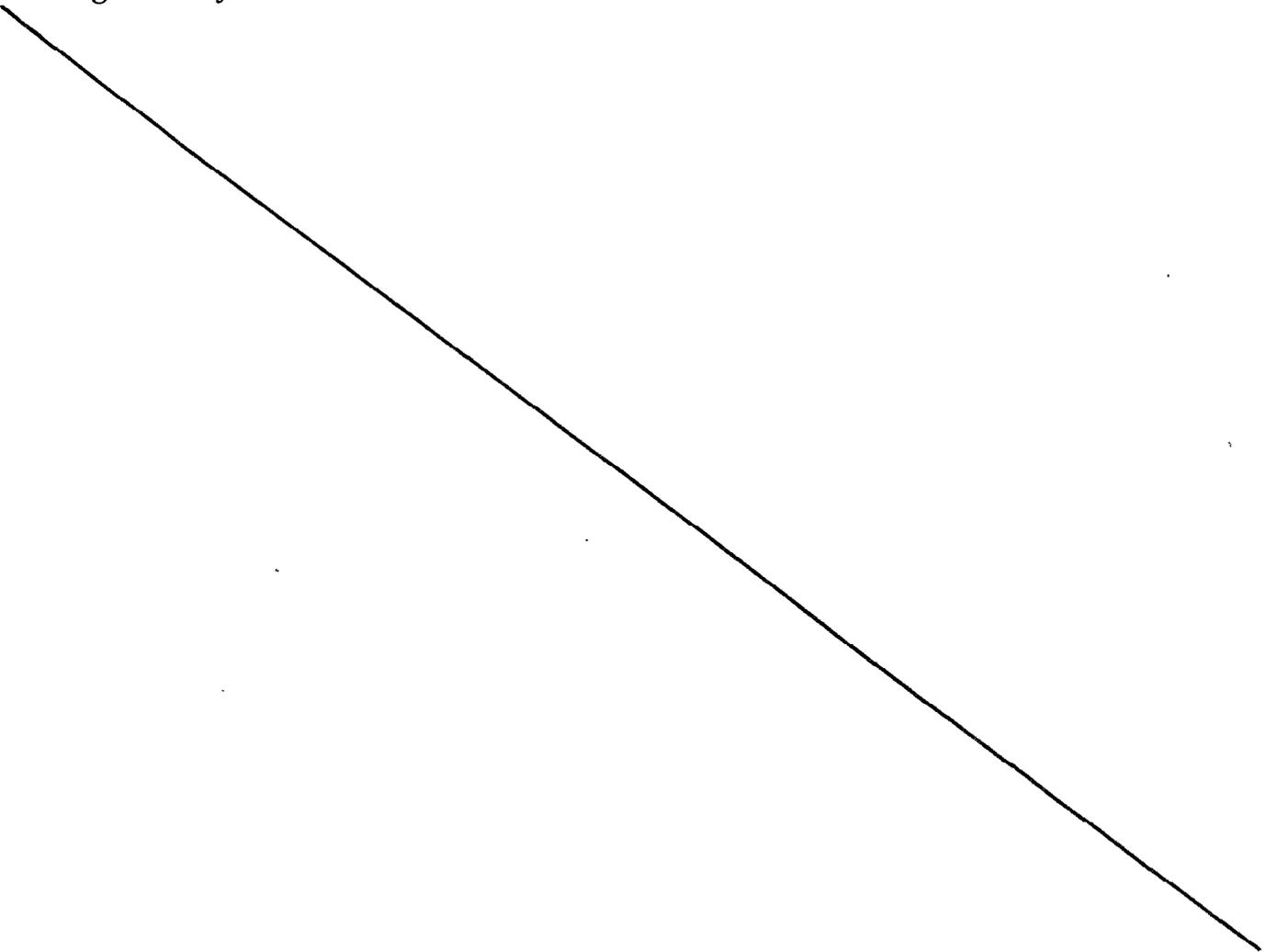
Guidance documents are prepared for FDA staff, applicants/sponsors, and the public that describe the agency’s interpretation of, or policy on, a regulatory issue. Every committee meeting includes an OPH during which interested persons may present relevant information or views orally or in writing 21 CFR 14.25(a). The hearing is conducted in accordance with 21 CFR 14.29. FDA encourages the participation from all public speakers in its decisionmaking processes. The draft guidance is intended to answer more fully questions about how (including topics such as meeting logistics and administrative requirements) the public may participate at an OPH session. This includes, but is not limited to, general members of the public; individuals or spokespersons from the regulated industry; consumer advocacy groups; and professional organizations, societies, or associations.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices (21 CFR 10.115). The draft guidance, when finalized will represent the agency’s current thinking on an FDA advisory committee open public hearing. 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 statute and regulations.

II. Comments

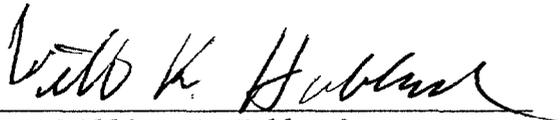
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found 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 <http://www.fda.gov/oc/advisory/default.htm> in the policy and guidance section of FDA's advisory committee Intranet Web site.

Dated: February 8, 2005
February 8, 2005.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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