Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail: *grjohnson@acf.hhs.gov*.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility, (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 8, 2005.

Robert Sargis,

Reports Clearance, Officer.

[FR Doc. 05–2826 Filed 2–14–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0042]

Draft Guidance on the Open Public Hearing; Food and Drug Administration Advisory Committee Meetings; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''The Open Public Hearing; FDA Advisory Committee Meetings.'' This draft guidance is for members of the public who choose to participate in the open public hearing (OPH) session of an FDA advisory committee meeting. The draft guidance is intended to answer more fully questions about how the public may participate at an OPH session, and it includes topics such as meeting logistics and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DATES: Submit written or electronic comments on this draft guidance by June 15, 2005. 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ADDRESSES: Submit written requests for single copies of the draft guidance to Linda Ann Sherman, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–2822 Filed 2–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0033]

Draft Guidance for Industry on Internal Radioactive Contamination—Development of Decorporation Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' This draft document provides guidance to industry on the development of decorporation agents for the treatment of internal radioactive contamination when evidence is needed to demonstrate the effectiveness of the agents, but human efficacy studies are unethical or infeasible. In such instances, the Animal Efficacy Rule may be invoked to approve new medical products not previously marketed or new indications for previously marketed products. Specifically, this draft guidance addresses chemistry, manufacturing and controls (CMC) information; animal efficacy, safety pharmacology, and toxicology studies; clinical pharmacology, biopharmaceutics, and human safety studies; and postapproval commitments.

DATES: Submit written or electronic comments on the draft guidance by May