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Draft Guidance on the Open Public Hearing; Food and Drug Administration Advisory Committee Meetings; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''The Open Public Hearing; FDA Advisory Committee Meetings.'' This draft guidance is for members of the public who choose to participate in the open public hearing (OPH) session of an FDA advisory committee meeting. The draft guidance is intended to answer more fully questions about how the public may participate at an OPH session, and it includes topics such as meeting logistics and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DATES: Submit written or electronic comments on this draft guidance by June 15, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to Linda Ann Sherman, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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

16, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stewart, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' This draft guidance is being issued to facilitate the development of new decorporation agents or new uses of previously marketed medical products for the treatment of internal radioactive contamination.

Internal radioactive contamination can arise from accidents involving nuclear reactors, industrial sources, or medical sources. The potential for such accidents has been present for many years. Recent events also have highlighted the potential for nonaccidental radioactive contamination as a result of malicious, criminal, or terrorist actions. Internal contamination occurs when radioactive material is ingested, inhaled, or absorbed from a contaminated wound. As long as these radioactive contaminants remain in the body, they may pose significant health risks. Long-term health concerns include the potential for the development of cancers of the lung, liver, thyroid, stomach, and bone and, when a radioactive contaminant is inhaled, for the development of fibrotic changes in the lung that may lead to restrictive lung disease. The only effective method of reducing these risks is removal of the radioactive contaminants from the body.

''Decorporation agents'' refer to medical products that increase the rate of elimination or excretion of inhaled, ingested, or absorbed radioactive contaminants. The effectiveness of most decorporation agents for the treatment of internal radioactive contamination cannot be tested in humans because the occurrence of accidental or nonaccidental radioactive contamination is rare, and it would be unethical to deliberately contaminate human volunteers with potentially harmful amounts of radioactive materials for investigational purposes.

FDA is issuing this draft guidance to facilitate the development of new decorporation agents or new indications for previously marketed medical products that may be eligible for approval under the Animal Efficacy Rule (21 CFR part 314, subpart I and 21 CFR part 601, subpart H). As set forth in this rule, under certain circumstances animal studies can be relied on to provide substantial evidence of effectiveness of a product. Evaluation of the product for safety in humans is still required, and cannot be addressed by animal studies alone. The adequacy of human safety data will need to be assessed from clinical pharmacology and safety studies conducted in humans. This draft guidance addresses the design and conduct of the requisite CMC, animal efficacy, safety pharmacology, toxicology, clinical pharmacology, biopharmaceutics, and human safety studies needed to support approval of new decorporation agents or new uses of previously marketed medical products for the treatment of internal radioactive contamination.

In addition, approval under the Animal Efficacy Rule is subject to certain postapproval commitments, including submission of a plan for conducting postmarketing studies that would be feasible should an accidental or intentional release of radiation occur, postmarketing restrictions to ensure safe use, if deemed necessary, and product labeling information intended for the patient advising that, among other things, the product's approval was based on effectiveness studies conducted in animals alone. This draft guidance addresses the postapproval commitments that would be needed for approval of a new decorporation agent or for a new indication for a previously approved agent under the Animal Efficacy Rule.

This draft 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 development of decorporation agents for the treatment of internal radioactive contamination. 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**) written or electronic comments on the guidance at any time. Two 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. The draft guidance and received comments are available for public examination 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/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2821 Filed 2–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: