number), written material and requests to make oral presentations, to the contact person by October 14, 2005. If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on October 7, 2005, via the Internet at *http://www.fda.gov/cder/meeting/ICH/ICH_fall2005.htm*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19017 Filed 9–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0375]

Stakeholder Meeting on the Implementation of A New Direction for the Food and Drug Administration's Radiological Health Program; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: A New Direction for FDA's Radiological Health Program. The topics of discussion are the agency's activities to implement its radiological health program (the program).

DATES: The public meeting will be held on October 31 and November 1, 2005, from 8:30 a.m. to 5 p.m. The agency is requiring registration by October 17, 2005.

All parties wishing to make a presentation or to speak on an issue specific to the topics of the meeting should indicate their intent, the topics to be addressed, and provide an abstract of their comments to be presented by October 17, 2005. FDA will limit the time for presentations to the public comment periods; the number of parties requesting to participate will determine the amount of time allotted to each presentation.

ADDRESSES: The public meeting will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Submit written requests to make an oral presentation to Kaye Chesemore (see **FOR FURTHER INFORMATION CONTACT**). Include your name, title, firm or organization name (if representing such), address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all requests for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kaye Chesemore, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3309, FAX: 301–594–3306, e-mail: *kfc@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In May 2004, FDA's Center for Devices and Radiological Health (CDRH) began an effort to examine how the program could best adapt to current public health needs. This effort culminated in a report that outlines key elements of the program and states how the new direction will impact the most pressing public health problems in the radiological health area. A copy of the report is available on CDRH's Web site at *http://www.fda.gov/cdrh/radhlth/initiative.html*.

The agency has determined that it must shift the focus of resources to the products and procedures with the highest risks to the public, including those that affect the greatest number of people or present the potential for the greatest harm.

The benefits that FDA expects from this focus are that the new program will:

(1) Align CDRH efforts with current and evolving public health needs,

(2) Expand focus on patient and consumer protection,

(3) Allow for a more targeted approach to FDA's programs and activities,

(4) Increase information dissemination and training, and

(5) Improve coordination across the radiological health community.

II. Agenda

On October 31, 2005, FDA is providing the opportunity for a number of stakeholder organizations to discuss how they can assist FDA in implementing the program and in addressing important public health problems. FDA and its stakeholders will discuss the following aspects of the radiological health plan overview:

• Standards—Discussion will consider the following topics: Increased reliance by FDA on consensus radiation safety performance standards, the role of national and international standards, and the role of State regulations in assuring product safety and proper use.

• Monitoring the Use of Radiation—Discussion will consider the following topics: The shift of CDRH's focus from products to users, patients, and consumers; adverse event reporting; State program roles in ensuring appropriate use of radiation; facility quality assurance programs; and the establishment of a voluntary patient radiation dose reporting system for diagnostic imaging procedures that use ionizing radiation. This system could be used to monitor national exposure trends and provide a basis for establishing diagnostic reference levels of patient dose for use in facility quality improvement programs.

• Monitoring the Industry—Discussion will consider the following topics: The shift of FDA emphasis from testing products, to inspecting manufacturers to assure quality manufacturing and products; the reduction of reporting requirements; and the development of electronic reporting methods.

• Education—Discussion will consider education and training for manufacturers, regulators, and users.

On November 1, 2005, FDA will hold concurrent discussion sessions throughout the day on the Standards, Monitoring, and Education topics to provide further opportunity for stakeholder comment and discussion.

FDA will provide an opportunity for comment during the public comment period for individuals and/or organizations on October 31, 2005. In addition, the agency will provide an opportunity to present individual viewpoints during the concurrent discussion sessions on November 1, 2005. FDA reserves the right to limit the time of speakers during the public comment periods.

III. Registration

Participants must register for the meeting by October 17, 2005. Acceptance will be on a first-come, first-served basis. There will be no onsite registration and unregistered participants will not be added to the program. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. Persons without Internet access may register for the onsite meeting by calling 301–594–3309 by October 17, 2005.

If you need special accommodations due to a disability, please fax information regarding those needs to Kaye Chesemore at 301–594–3306, at least 7 days in advance of the meeting.

IV. Request for Suggestions, Recommendations, and Materials

FDA is particularly interested in receiving suggestions from stakeholders related to the topics listed previously in this document. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives in the docket for this document (2005N–0375). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19077 Filed 9–20–05; 3:31 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8000]

Memorandum of Understanding Between the Food and Drug Administration and the Food and Drug Administration Alumni Association

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Food and Drug Administration Alumni Association, Inc. The purpose of this MOU is to establish a greater collaboration between FDA and the Food and Drug Administration Alumni Association, Inc., regarding FDAs 2006 Centennial Observance.

DATES: The agreement became effective July 28, 2004.

FOR FURTHER INFORMATION CONTACT: Mary Hitch, Senior Advisor, Office of External Relations (HF–10), 5600 Fishers Lane, Rockville, MD 20857, 301–827–4406.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S