

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Electronic Health Records Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 18th meeting of the American Health Information Community Electronic Health Records Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.)

DATES: September 25, 2007, from 1 p.m. to 4 p.m. [Eastern]

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090. Please bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: <http://www.hhs.gov/healthit/ahic/healthrecords>.

SUPPLEMENTARY INFORMATION: The Workgroup will continue its discussion on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.

The meeting will be available via Web/cast. For additional information, go to: http://www.hhs.gov/healthit/ahic/healthrecords/ehr_instruct.html.

Dated: August 7, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07-3932 Filed 8-10-07; 8:45 am]

BILLING CODE 4150-24-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Chronic Care Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 18th meeting of the American Health Information Community Chronic Care Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.).

DATES: September 27, 2007, from 1 p.m. to 4 p.m. Eastern Daylight Time.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC

20201), Conference Room 4090. Please bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: <http://www.hhs.gov/healthit/ahic/chroniccare/>.

SUPPLEMENTARY INFORMATION: The Workgroup will discuss barriers to availability of care in the virtual setting.

The meeting will be available via Web cast. For additional information, go to: http://www.hhs.gov/healthit/ahic/chroniccare/cc_instruct.html.

Dated: August 7, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07-3933 Filed 8-10-07; 8:45 am]

BILLING CODE 4150-24-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Fourth National Study of Older Americans Act Recipients

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 12, 2007.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.6974 to the OMB Desk Officer for AoA, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Valerie Cook (202) 357-3583 or Valerie.Cook@aoa.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, AoA has submitted the following proposed collection of information to OMB for review and clearance.

The Fourth National Survey of Older Americans Act Service Recipients builds on earlier national studies and performance measurement tools developed by grantees in the Performance Outcomes Measures Project (POMP). It will include

consumer assessment surveys for congregate and home delivered meal nutrition program, transportation, homecare services and other title IIIB services, and National Family Caregiver Support Program. Copies of the POMP instruments can be located at <http://www.gpra.net>. Information collected through the study will be used by AoA to track performance outcome measures, support budget requests; comply with Government Performance Results Act (GPRA) reporting requirements; provide information for OMB's program assessment (PART) process; provide national benchmark information for grantees and inform program improvement and management initiatives.

AoA estimates the burden of this collection of information as follows: 250 Area Agencies on Aging will have to commit 4 hours each for identifying potential clients to be interviewed for the survey. The estimated burden is 1,000 hours. 6,000 individuals will be surveyed about their usage and satisfaction with services. Each interview takes approximately 30 minutes for an estimated burden of 3,000 hours. Total burden of data collection is 4,000 hours.

Dated: August 8, 2007.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. E7-15820 Filed 8-10-07; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0211]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submitting and Reviewing Complete Responses to Clinical Holds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Submitting and Reviewing Complete Responses to Clinical Holds" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 25, 2006 (71 FR 30142), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0445. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-15740 Filed 8-10-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0304]

Preparation for International Conference on Harmonization Meetings in Yokohama, Japan; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH meetings in Yokohama, Japan" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Yokohama, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Yokohama, Japan, October 27 through November 1, 2007, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on Wednesday, October 10, 2007, from 12:30 p.m. to 3 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Room D and E, Rockville, MD 20857. For security reasons, all attendees are

asked to arrive no later than 12:20 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Room D and E.

Contact Person: All participants must register with Tammie Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: Tammie.Bell2@fda.hhs.gov or fax: 301-827-0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person by October 8, 2007.

If you need special accommodations due to a disability, please contact Tammie Bell at least 7 days in advance.

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.

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 (IFPMA). 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 4:30 p.m. and 5 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 April 2, 2007, and submit a brief statement of the general nature of the evidence or arguments they wish 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 via the internet at http://www.fda.gov/cder/meeting/ICH_20060508.htm.

Dated: August 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-15803 Filed 8-10-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0313]

Preparation for International Cooperation on Cosmetics Regulations Meeting in Brussels, Belgium; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for International Cooperation on Cosmetics