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 12:30p.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 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 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

Regulations (ICCR) Meeting in Brussels, Belgium'' to provide information on the process and receive comments on issues that may be relevant to discussions being held at the ICCR meeting in Brussels, Belgium. The purpose of the meeting is to solicit public input prior to the first meeting of this group in Brussels on September 27, 2007.

Date and Time: The meeting will be held on Tuesday, August 28, 2007, from 2 p.m. to 3:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd fl., Chesapeake Conference Room, Rockville, MD 20857. For security reasons, all attendees must preregister and are asked to arrive no later than 1:50 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Chesapeake Conference Room.

Contact Person: All participants must register with Michelle Limoli, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *michelle.limoli@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), and written material and requests to make oral presentations, to the contact person by August 21, 2007.

If you need special accommodations due to a disability, please contact Michelle Limoli 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. 6–30, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. It should be noted that the definition and regulatory classification of ''cosmetics'' in the different countries/regions is not identical. For this reason, the ICCR will consider some U.S. over-the-counter drugs that are regulated as ''cosmetics'' outside the United States. ICCR members are: the Food and Drug Administration of the United States of America; the Ministry of Health, Labour, and Welfare of Japan; the European Commission Directorate General Enterprise; and Health Canada. This multilateral framework was created to identify ways to remove regulatory obstacles among the regions, while maintaining the highest level of global consumer protection. The first meeting of the group will occur in Brussels, Belgium, September 27, 2007.

The ICCR will operate on a consensus basis whereby all decisions of the representatives of the regulatory members and subsequent actions must be taken by consensus. Members agree to take steps as appropriate to implement the items that have reached consensus within the boundaries of their legal and institutional constraints. In this respect, they agree to promote the documents reflecting the consensus within their own jurisdictions and to seek convergence of regulatory policies and practices.

The members' responsibilities will include providing overall strategic guidance and direction to activities of ICCR; defining subject areas for ICCR activities and deciding on future topics for activity; exchanging information on regulatory, trade, and market developments of interest; determining policies related to the ICCR process, administration, and external communications; appointing ad-hoc working groups to carry out technical work as needed; adopting guidelines and policy statements, including those developed by the ad-hoc working groups; and taking on any other initiatives that contribute to achieving ICCR objectives.

It is recognized that successful implementation requires the input of a constructive dialogue with the cosmetics' industry trade associations and other relevant stakeholders, hence the scheduling of this public meeting.

The industry trade associations of each region will gather input in order to represent all affected industry sectors on specific issues at ICCR meetings. Prior to ICCR meetings, well in advance to allow adequate time for preparation, industry will suggest items for priority actions to be consider by ICCR members. During the ICCR meeting, industry trade associations will enter in a constructive dialogue with the members and give their opinion and directions for future work.

According to specific needs, ICCR working groups may be established with a precise mandate on an ad-hoc and temporary basis by the members. Working groups are created primarily for the purpose of developing proposed guidelines and policy statements for adoption by the members. The working group participants are appointed by consensus of the members. Outside technical experts may be invited on an as-needed basis.

The ICCR will meet at least once per year, but may alter the frequency of meetings if considered necessary to ensure progress. The venue of meetings rotates among the territory of the four members.

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 p.m. and 3:30 p.m. Time allotted for oral presentations may be limited by the numbers requesting to speak; however no more than 10 minutes will be allotted per speaker. Those desiring to make oral presentations should notify the contact person by August 24, 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.

Dated: August 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3954 Filed 8–9–07; 1:38 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Drug Accountability Record

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Cancer Institute (NIH) will publish periodic summaries to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Drug Accountability Record (Form NIH 2564).

Type of Information Collection Request: Extension, with no Changes OMB No. 0925–0240, Expiration Date 11/30/07.

Need and Use of Information Collection: Food and Drug Administration (FDA) regulations require investigators to establish a record of the receipt, use and disposition of all investigational agents. The National Cancer Institute, (NCI) as a sponsor investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill