

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[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.

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**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.

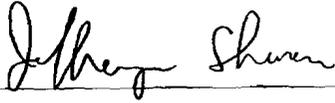
The ICCR will meet at least once per year, but may alter the frequency of meetings if considered necessary to ensure progress. The venue of meetings rotates among the territory of the four members.

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: AUG 8 2007

August 8, 2007.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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