

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2008-N-0138] (formerly Docket No. 2007N-0313)

Outcome of Meeting of the International Cooperation on Cosmetic Regulation, September 26-28, 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the International Cooperation on Cosmetic Regulation (ICCR) Outcome of Meeting, September 26-28, 2007. This notice is in keeping with an FDA/ICCR commitment to transparency as well as providing opportunity for public comment.

DATES: To ensure that the agency considers your comment on this ICCR outcome of meeting, please submit written or electronic comments on the outcome of meeting by July 2, 2008.

ADDRESSES: Submit written comments 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.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Michelle Limoli, Office of the Commissioner, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, rm. 15A-55, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

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I. Background

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, ICCR will consider some U.S. over-the-counter drugs that are regulated as “cosmetics” outside the United States. ICCR members are: FDA; the Ministry of Health, Labor, 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 group meeting occurred in Brussels, Belgium, September 26–28, 2007.

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. Well in advance of ICCR meetings (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, on an ad-hoc and temporary basis members may establish ICCR working groups with a precise mandate. 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.

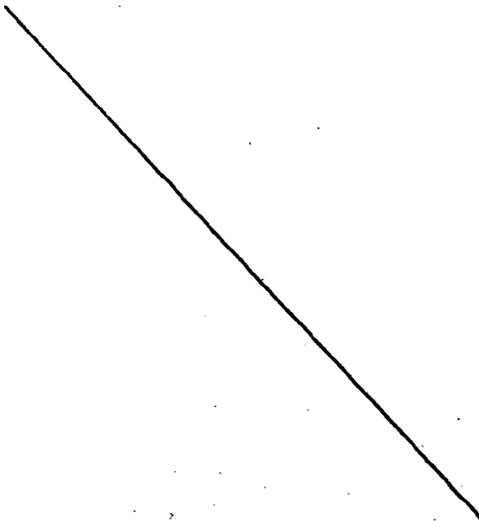
ICCR will meet at least once per year, but may alter the frequency of meetings if considered necessary to ensure progress. The venue of meetings rotates among the territory of the four members.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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.

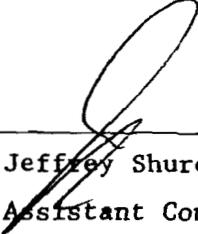
Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.



III. Electronic Access

Persons with access to the Internet may obtain the outcome of meeting document at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 2/29/08
~~February 29, 2008.~~



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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Dawn P. Hawkins