

Transcripts: As soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It also may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. You should send written requests for a hardcopy or CD-ROM transcript to the Division of Freedom of Information, (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Directorate General for Health and Consumers; the Ministry of Health, Labor and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

You may present data, information, or views orally or in writing on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by April 22, 2013, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate time you need to make your presentation. If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (*see Contact Person*) by May 1, 2013.

We will make the agenda for the public meeting available on the Internet at: <http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/International>

Cooperation on Cosmetics Regulations ICCR/default.htm. We may use the information that you provide to us during the public meeting to help us prepare for the July 8 to 10, 2013 ICCR-7 meeting.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07949 Filed 4-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 8, 2013, from 1 p.m. to approximately 4 p.m.

Location: Rockwall II, Conference Room 1033, 5515 Security Lane, Rockville, MD 20852. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/>

default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 8, 2013, the committee will meet in open session to hear updates of the research programs in the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 8, 2013, from 1 p.m. to approximately 3:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 1, 2013. Oral presentations from the public will be scheduled between approximately 2:20 p.m. and 3:20 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 23, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 24, 2013.

Closed Committee Deliberations: On May 8, 2013, from approximately 3:20 p.m. to approximately 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss

the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 2, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-07961 Filed 4-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

2013 Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2013 Medical Countermeasures initiative (MCMi) Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Dates and Times: The symposium will be held on May 29 and May 30, 2013, from 9 a.m. to 5 p.m., and on May 31, 2013, from 9 a.m. to 12 noon. Persons interested in attending the

symposium in person or viewing via Webcast must register by May 24, 2013, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the symposium participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact: Rakesh Raghuvanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4283, Silver Spring, MD 20993, 301-796-4769, Fax: 301-847-8615, email: AskMCMi@fda.hhs.gov.

Registration: If you wish to attend the symposium or view via Webcast, you must register at <http://www.fda.gov/medicalcountermeasures> by May 24, 2013, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please enter pertinent information in the "Notes" section of the electronic registration form when you register.

Date: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07893 Filed 4-4-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Society of Clinical Research Associates-Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The conference on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents, and regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

DATES: Date and Time: The conference will be held on May 15 and 16, 2013, from 8 a.m. to 5 p.m.

Location: The conference will be held at the Renaissance Seattle Hotel, 515 Madison St., Seattle, WA 98104.

Contact Person: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510-287-2708, FAX: 510-287-2739; or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800-762-7292, FAX: 215-822-8633, email: SoCRAmail@aol.com, Web site: www.socra.org.

Registration and Meeting Information: See SOCRA Web site, www.SoCRA.org. http://www.socra.org/html/FDA_Conference.htm. Registrations fees are as follows: \$575.00 for SOCRA members; \$650.00 for nonmembers (includes membership); \$450.00 for Federal Government members; \$525.00 for Federal Government nonmembers; FDA employee rate is fee-waived. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. If you need special accommodations due to a disability, please contact Jane Kreis (see **Contact Person**) at least 10 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board inspections, electronic record