

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Processing Methods for Orthopedic, Cardiovascular, and Skin Allografts;

Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Office of Regulatory Affairs (ORA) and the Centers for Disease Control and Prevention (CDC) are announcing a public workshop entitled "Processing Methods for Orthopedic, Cardiovascular, and Skin Allografts." The purpose of the public workshop is to discuss various methods used to process tissue allograft, pre- and post-processing cultures, and disinfection and sterilization of tissues.

Date and Time: The public workshop will be held on October 11, 2007, from 8:30 a.m. to 5 p.m., and October 12, 2007, from 8:30 a.m. to 1 p.m.

Location: The public workshop will be held at the Masur Auditorium, Building 10 Clinical Center, National Institutes of Health, Bethesda, MD 20892.

Contact: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, e-mail: CBERTrainingSuggestions@fda.hhs.gov (Subject line: Tissue Processing Workshop).

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Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by September 18, 2007. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact*) at least 7 days in advance.

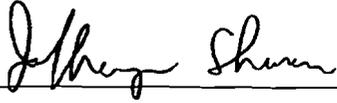
SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by experts from the government, the medical field and the tissue industry. The first day of the workshop will include discussions on: (1) Surgeon clinical practices, experiences, expectations, and assumptions regarding tissue allografts and patient safety; and (2) Pre- and Post-Processing cultures for microorganisms—usefulness, reliability, and validation. The second day of the workshop will focus on disinfection and sterilization of tissues—experiences, expectations, and challenges.

Transcripts: Transcripts of the public workshop 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 public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

AUG 10 2007

Dated: _____

August 10, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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