

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 97N-0068]

**FDA Tissue Reference Group—The Process; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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The Food and Drug Administration (FDA) is announcing a public workshop entitled "FDA Tissue Reference Group—The Process." This public workshop is intended to provide information about the tissue reference group history, process, and other related matters. The FDA public workshop follows the American Association of Tissue Banks annual meeting held from August 25 to August 28, 2001.

*Date and Time:* The public workshop will be held on August 29, 2001, from 9:30 a.m. to 11:30 a.m.

*Location:* The public workshop will be held at the Marriott Wardman Park Hotel, 2660 Woodley Rd. NW., Washington, DC 20008.

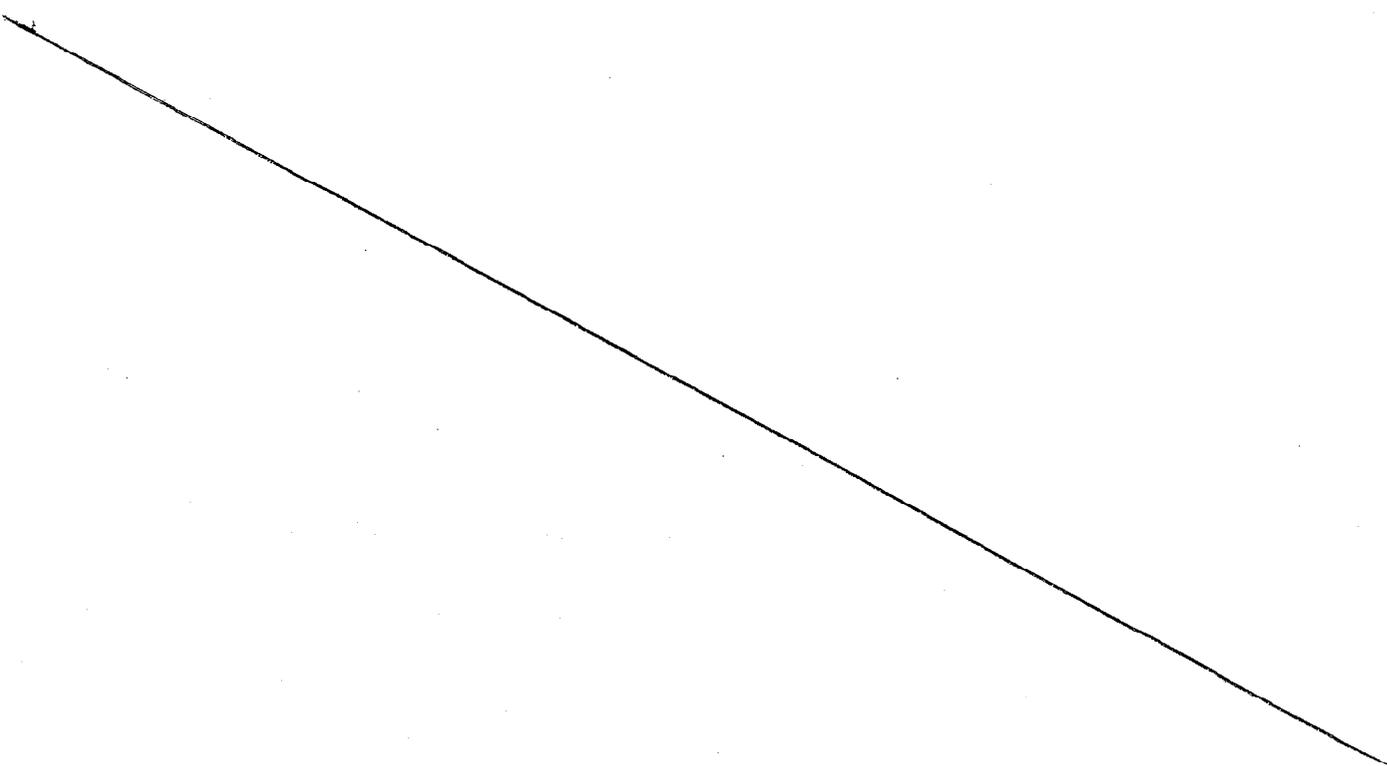
*Contact:* Martha Wells, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6106, or Ruth Solomon (address above), 301-827-6107, FAX 301-827-2844.

*Registration:* No preregistration is required. Registration at the site will be done on a space available basis on the day of the public workshop, beginning at 8:30 a.m. There is no registration fee. If you need special accommodations due to a disability, please contact Martha Wells at least 7 days in advance.

*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. 12A-

16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 per page. The public workshop transcript will also be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

**SUPPLEMENTARY INFORMATION:** The Tissue Reference Group (TRG) is part of the Tissue Action Plan, which was developed to implement the "Proposed Approach to the Regulation of Cellular and Tissue-based Products" dated February 28, 1997 (62 FR 9721, March 4, 1997). The purpose of the TRG is to provide a single reference point for product specific questions from sponsors or their designated representatives about jurisdiction, policy, and regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The agenda for the public workshop includes the following: (1) History of the TRG; (2) TRG process for making recommendations to the FDA Center Directors; (3) request for designation process; (4) confidentiality and the Freedom



of Information Act process; and (5) factors for regulation of HCT/Ps solely under section 361 of the Public Health Service Act. The public workshop information is posted on the Internet at <http://www.fda.gov/cber/meetings/trgproc082901.htm>.

Dated: 8.8.01

August 8, 2001.

*Margaret M. Dotzel*

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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*Namoni Oliver*

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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