Once you obtain your account ID and password, you will enter them and log into FURLS. From the FURLS/FDA Industry Systems menu, there will be a button that you will click to go to the Device Registration and Listing Module (DRLM) of FURLS. New establishments will register their establishment and existing establishments will re-register their establishments using choices on the DRLM menu. Once you make your selection—either Register a Facility or Annual Re-registration—the system will prompt you through the entry of information about your establishment and your devices.

If you have any problems with this process you may call 240–276–0111 for assistance. (Note: This phone number is for assistance with establishment registration and establishment fee payment only, and not for any other aspects of medical device user fees.)

B. Step Two—Determine Whether an Annual Registration Fee is Required and Get Your Invoice if a Fee is Due

After you enter your establishment registration information into the system, you will be informed whether or not the payment of an annual registration fee is required to complete your registration (these fees are only required for device manufacturers, single-use re-processors, and specification developers as stated in section I of this document). If your establishment is subject to a fee, you will be given a summary sheet that: (1) Tells you what your payment options are and (2) leads you to a link for your specific invoice, which will be available on-line as a portable document format (PDF) file that you should print copies of; one to submit with your payment (if not submitted electronically) and the other to keep for your records.

C. Step Three—Pay Your Invoice, if Required

Make the payment, if required, in U.S. currency. The summary page will include payment information that may permit you the option of paying electronically. If that option is provided, you may follow the instructions provided to make payment electronically. If that option is not provided, or you choose not to make your payment electronically, you may pay by check.

Your check, made in U.S. dollars and drawn on a U.S. bank, can be mailed to: Food and Drug Administration, P.O. Box 70961, Charlotte, NC 28272–0961. (Please note that this is different than the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration—Lockbox 70961, rm. NC0810, 1525 West WT Harris Blvd., Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only; do not send mail to this address.)

Please make sure that the FDA post office box number (P.O. Box 70961) is written on the check, along with the invoice number printed on your invoice. A copy of your printed invoice should also be mailed in the same envelope with your check. FDA's tax identification number is 53–0196965.

Wire transfers may also be used to pay annual establishment fees. The routing and transit number is 021030004 and the account number is 75060099. The invoice number should also be included with any wire transfer information, to assure that the invoice is properly credited.

FDA is in the process of implementing alternate Web-based payment methods, and the option of electronic payment may not be immediately available for FY 2008 payments. For more information on these payment options and when they will be available, please visit FDA's Web site at *http://www.fda.gov*, select the appropriate user fee type, and click on ''User Fee Cover Sheet.''

Dated: October 4, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

In Vitro Analysis of Cell/Scaffold Medical Products; 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 and Center for Devices and Radiological Health, and the National Institute of Standards and Technology are announcing a public workshop entitled: In Vitro Analysis of Cell/Scaffold Medical Products. The purpose of the public workshop is to discuss issues that should be considered when evaluating cell/scaffold medical products and to determine which test methods are currently available and which new analytical procedures should be further researched for the evaluation of cell/scaffold medical products.

Date and Time: The public workshop will be held on December 6 and 7, 2007, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at the National Transportation and Safety Board, 490 L'Enfant Plaza East, SW., Washington, DC 20594.

Contact Person: 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: *CBERTraining@fda.hhs.gov* (Subject line: Tissue Engineering Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by November 15, 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 Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by experts from the medical field and the government. The first day of the workshop will include discussions on in vitro assays of product performance. The second day of the workshop will include discussions on tools for quantifying the response of cells and tissues.

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*.

Dated: October 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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