Establishment Registration Tool:
Electronic Completion of eHCTERS

This provides step-by-step instructions for completing Establishment Registration through the FDA’s electronic portal. For additional information on the Establishment Registration program, terms used, interpretation of regulations, and what it may mean for your facility, please refer to the document: A00455, Establishment Registration: General Information.

How to Register:
Registration is completed electronically using the eHCTERS on-line process though a secure web server. Information on this process and the requirements for registration may be found at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm

This portal is used for Blood Establishment Registration (form FDA 2830), Tissue Establishment Registration (form FDA 3356), and Biological Product Deviation Reporting (form FDA 3486). Instructions for the registration are available on the first page on entry for the on-line registration form. When each screen has been completed, select CONTINUE or NEXT on the bottom of the page.

1. First-time users to the CBER On-Line Login Screen have assistance available to set up user information. Create a user name and a password to secure entry into the system. The same user name will be used from year to year for the annual registration renewal. Be sure to record this information for future reference.

Repeat users enter the user name and password, and then must select “eHCTERS (Tissue Establishment Registration)” from a drop down box. Select “Login.”

2. The Activity Selection screen provides the following options:
   a. Initial Registration
   b. Edit a Validated Form
      i. Annual Registration
      ii. Change in information
      iii. In-activate registration
   c. Complete Unfinished form 3356

Select the appropriate option. If multiple facilities registered under a single user name, there is a drop-down box to select from existing user establishments. Return to an incomplete registration by entering a previously documented Confirmation Number. When a selection is made, press CONTINUE.

3. Edit Establishment Registration Information: Link other FDA registrations to the current registration by checking the appropriate option (blood, device, or drug establishments) if applicable. Also, select if this is an annual registration or a change in information. Press NEXT.
4. **Address Information**: Certain fields are required and instructions are provided for telephone number completion for international country codes. There is an option identified as a “satellite recovery establishment.” Refer to the instructions for a description of this option; however this does not apply to establishments registering for the NMDP. There is also an option to check if a location tests for microorganisms only. Press NEXT.

5. **Reporting Official**: This is the person appointed by the owner or operator of the facility to register the establishment and answer correspondence related to the registration. The reporting official serves as the contact for the establishment and verifies that information is accurate to the best of his or her knowledge.

   **NOTE**: All communication from FDA with the facility will be via email to the Reporting Official. If the staff person changes, be sure the responsibility for communication with FDA is reassigned.

   Enter complete information and press NEXT.

6. For domestic centers, a **U.S. Agent** is not required. The option to enter a U.S. Agent is bypassed for establishments within the United States.

   **U.S. Agent** applies only to international establishments. The primary responsibility of the U.S. agent is to provide the FDA with a U.S. contact should U.S. Customs have a question about a product that has arrived at a U.S. port of entry. It is also intended to provide the FDA with a U.S. contact if the FDA needs to inspect the international center.

   **NOTE**: International facilities that export products only through the NMDP may name Dr. John Miller as the U.S. Agent. Facilities that export additional products to the U.S. not specifically through the NMDP must name someone other than Dr. Miller as the U.S. Agent.

   To identify Dr. John Miller as the U.S. Agent, enter:

   i. **First Name**: John  
      **Last Name**: Miller, M.D.  
      **Title**: Senior Medical Director

   ii. **E-Mail Address**: jmiller5@nmdp.org  
       **Phone**: 612-627-5800  
       **Institution Name**: National Marrow Donor Program (NMDP)  
       **Street Address**: 500 N 5th Street  
                        **Attention**: John Miller, M.D.

   **City**: Minneapolis  
   **State**: Minnesota  
   **Postal Code**: 55401

   **NOTE**: If Dr. John Miller is identified as the U.S. Agent, when the Reporting Official receives the verified form from the FDA, a copy of the validated form must be forwarded to NMDP. See NMDP contact information at the end of this document.

7. **HCT/P Listing Information**: Check all products manufactured at the registered facility. There are three column options:

   a. **HCT/Ps described in 21 CFR 1271.10**
b. HCT/Ps Regulated as Medical Devices

c. HCT/Ps Regulated as Drugs or Biological Drugs

Autologous products or products from first or second-degree related donors are described in 21 CFR 1271.10. Some centers collect first or second-degree related donors for the NMDP and would mark this category.

Allogeneic products from unrelated donors manufactured for the NMDP fall under the category of HCT/Ps regulated as drugs or biological drugs. All NMDP centers collecting HPC, Apheresis would mark this category.

Proprietary names only apply to licensed products. Some cord blood banks hold licenses for cord blood units, but no HPC, Apheresis products would have proprietary names.

Note: For facilities that manufacture MNC, Apheresis products, the FDA requests that products are listed as “Therapeutic Cells.” To add this to the product list, select “Add Other HCT/Ps” at the bottom of the screen. A new table will appear. Select “Therapeutic Cells” from the drop-down box under Type of HCT/P. Then complete the HCT/P listing information for that product as above. To return to the previous screen, select “Add and Return.”

International centers must list only the products that are exported to the United States. Other products that are not exported to the U.S. must not be included on this form.

Review the completed list of HCT/Ps, and when correct, press NEXT.

8. HCT/P Function Information: Check only the steps in manufacturing performed at the listed facility.

Note: “Test” and “Screen” refer to the donor testing and screening and not product testing. Refer to Establishment Registration: General Information (A00455) or the instructions provided by the FDA for more complete descriptions of the manufacturing terms.

9. Donor Information: In this section, specify Autologous or Allogeneic. It is not possible to specify an allogeneic donor for therapeutic cells. This is acceptable to the FDA. Press NEXT.

10. Additional Information: Space is provided allowing text entry. This may be left blank.

11. Preview: This is a summary of your information. Information has not yet been submitted. Take the time to review to ensure it is complete and accurate.

When review is complete, select “Submit to FDA.” This will complete the process. A summary will be displayed with the information that was submitted. This screen will also contain the Confirmation Number. This information can be printed to record the submission, and the Confirmation Number may be used as a reference until the verified form is received from the FDA.

After the information has been validated at the FDA, a copy of the completed form 3356 will be sent via email to the Reporting Official. This will include the date of validation and the Field Establishment Identifier (FEI). The FEI number will be the identifier for the listed facility for communications going forward. This validated form should be available.
to show that registration is accurate and current. It may take up to several weeks for this process to be completed before the FDA sends the validated form 3356.

If Dr. Miller was listed as the US Agent, please send/email a copy of this validated form to the NMDP. Send a copy of this validated form to your liaison or to the Regulatory Compliance Specialist listed at the end of this document.

Contacts:
The FDA Tissue Establishment Registration Coordinator may be contacted via email at tissuereg@fda.hhs.gov or by phone at (301) 827-6176 with comments or questions concerning Human Cell and Tissue Establishment Registration. There are also links to instructions on the eHCTERS screen for more information or technical support through the registration process.

Tissues and Tissue Products:
http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm

NMDP contact:
Lori Hanley, Regulatory Compliance Specialist
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