Establishment Registration Tool:
Electronic Completion of eHCTERS

Purpose: To provide instructions for completing Establishment Registration through the Food and Drug Administration (FDA) electronic portal.

For additional information on the Establishment Registration program, terms used, interpretation of regulations, and what it may mean for your facility, refer to 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: https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=14371273&CFTOKEN=3bf68105249a55d0-A85D0D0F-1372-5AE1-674338933A9DF71D.

The 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 registration available at: https://www.fda.gov/media/109160/download.

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 username and a password to secure entry into the system.

   NOTE: The same username will be used from year to year for the annual registration renewal. Record this information for future reference. The password expires every 60 days. If password has expired, the system will assist you to create a new password. Always record this for future reference.

   There is an explanation of government security expectations and privacy expectations before proceeding. You are expected to read this information and click the "I understand" statement before you can proceed.

   Returning users enter the username and password and 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 Registration: Pre-confirmation number must be provided.

   Select the appropriate option. If multiple facilities registered under a single username, 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, select **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. Select **NEXT**.

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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 National Marrow Donor Program® (NMDP)/Be The Match®. There is also an option to check if a location tests for microorganisms only. Select **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. Enter complete information and select **NEXT**.

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

6. **U.S. Agent:** This only applies 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.

   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.

   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.

   a. 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 your facility identifies Dr. John Miller as the U.S. Agent, the Reporting Official must send a copy of the validated registration form to NMDP**.** See NMDP contact information at the end of this document.

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7. **Establishment Importer Information:** This screen only appears for international establishments. This should be the name of the transplant center within the U.S. that will receive the product. There can be multiple importers named on a registration. This requires the name, address, contact person and contact information including phone and email. The NMDP cannot be listed.

    - An international facility that collects a product from a related donor must register, or update their registration to identify the transplant center intended to receive the product
    - If additional products are collected through the year from related donors being sent to other transplant centers, the registration must be updated.
    - Contact your Case Manager, or the NMDP contact listed at the end of this document for questions.

8. **HCT/P Listing Information:** Check all products manufactured at the registered facility.

    - HCT/Ps described in 21 CFR 1271.10

    Autologous products or products from first or second-degree related donors are described in 21 CFR 1271.10. Only centers collecting first or second-degree related donors for the NMDP would select this category.

    Proprietary names only apply to licensed products. Leave this blank.

    Note: Products likely to be listed are HPC, Apheresis, and Peripheral Blood Mononuclear Cells.

    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, select **NEXT**.

9. **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 A00455, *Establishment Registration: General Information* or the instructions provided by the FDA for more complete descriptions of the manufacturing terms.

10. **Donor Information:** In this section, specify Autologous or Family Related. Select **NEXT**.

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

12. **Preview:** This is a summary of the information entered. Information has not yet been submitted to the FDA. Review the summary to ensure it is complete and accurate. When review is complete and information is accurate, select "**Submit to FDA.**"

    There is an attestation statement for the Reporting Official, and the information is confirmed by entering the Reporting Official's email address. 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.

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Post Registration:

After the information has been validated at the FDA, a copy of the completed form FDA 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 for inspection 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 FDA 3356.

If Dr. John Miller was listed as the U.S. agent, send/email a copy of this validated form to the NMDP. The validated form can be sent to your liaison or to the Regulatory Compliance Specialist listed at the end of this document.

Contacts:

The FDA **Tissue Registration Coordinator** may be contacted via email at tissuereg@fda.hhs.gov with comments or questions concerning Human Cell and Tissue Establishment Registration.

Tissues and Tissue Products:

http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm

NMDP Contact: Regulatory Compliance: regulatory@nmdp.org

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