U.S. FDA Establishment Registration: International Centers
Description and Instructions
About FDA Establishment Registration

International centers that export cord blood, PBSC, or lymphocytes to the United States register with FDA.

Bone marrow is not included in this requirement.

- Registration must be renewed every December.
How do I register?

  - Search: Tissue Establishment Registration
  - CBER On-Line - Login Screen
    - eHCTERS

What happens if I don’t register?

- Product denied or delayed entry into the U.S.
- Potential fines
- You can no longer do business with the U.S.
Operated by the National Marrow Donor Program®

Enter “Tissue Establishment Registration”, then press Search
Create a new account. **Record the User Name and Password.** It will be necessary to have that information for annual registration every December.
Registration Tips

• **Record the User Name and Password** in a safe place. This information will be required to access registration information for any updates and for annual renewal *every December*.

• **Reporting Official:** Person identified to complete registration and communicate with FDA.

• **U.S. Agent:** Contact person in U.S. to facilitate communication with FDA
  – Contacted if there is a U.S. Customs question regarding a product arriving at a U.S. Port of Entry
  – Facilitates communication if FDA plans to inspect facility
Select options

To go to the next screen, select “Continue”
Every December, registration must be renewed.
Complete the Information for your Facility. Update as Needed.
Reporting Official

- The Reporting Official does not need to be the medical director
- FDA communicates with your facility via email with your Reporting Official
- FDA sends a reminder to the Reporting Official in November to complete the annual renewal in December
- If this person changes, update your registration or the FDA communications will be lost
Reporting Official: person who will communicate with FDA, and complete annual registration renewal.
U.S. Agent

• Non-U.S. facilities must name a U.S. Agent
• This person serves as a U.S. contact for your facility
  – if U.S. Customs has a question about a product coming into the U.S., or
  – if the FDA would need to inspect a facility
U.S. Agent

- If you export to the U.S. for products **only** through NMDP, you may identify Dr. John Miller as your U.S. Agent: John Miller, M.D., Ph.D.
  National Marrow Donor Program
  500 North 5th Street
  Minneapolis, MN 55401 USA
  jmliller5@nmdp.org
  1-763-406-5800

- If your products are also sent via direct arrangements with a transplant center, you may **NOT** use Dr. Miller as your U.S. Agent.
Mark products “manufactured” at your facility sent to the U.S. through NMDP

Mark this column for NMDP products

Only list products sent to the U.S.
What is “Manufacturing?”

- Any of the following steps:
  - **Recover**: collection by apheresis or the collection of a cord blood unit
  - **Screen**: deciding if an adult donor or cord blood donor is acceptable
  - **Package**: placing a product in a bag and/or shipping container
  - **Process**: perform bacterial or fungal cultures, cryopreservation, other
  - **Store**: keep a product overnight or longer
  - **Label**: completing a product label or additional materials about the product or contents
  - **Distribute**: making a product available for transplant (does not include actual transport or carrying the product)
NMDP only facilitates allogeneic donors
Additional information may be added as needed.
Review information for accuracy
### HCT/P Listing Information

<table>
<thead>
<tr>
<th>Types of HCT/Ps</th>
<th>HCT/P's Described in 21 CFR 1271.10</th>
<th>HCT/P's Regulated as Medical Devices</th>
<th>HCT/P's Regulated as Drugs or Biological Drugs</th>
<th>Proprietary Names</th>
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<tbody>
<tr>
<td>a. Bone</td>
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<td>b. Cartilage</td>
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<td>c. Cornea</td>
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<td>d. Dura Mater</td>
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<td>e. Embryo</td>
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<td>f. Esophagus</td>
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<td>g. Heart Valve</td>
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<td>h. Ligament</td>
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<td>i. Oocyte</td>
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<td>j. Pericardium</td>
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<td>k. Peripheral Blood Stem Cells</td>
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<td>l. Sclera</td>
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<td>n. Skin</td>
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<td>o. Somatic Cell Therapy Products</td>
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<td>p. Tendon</td>
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<td>q. Umbilical Cord Blood Stem Cells</td>
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<td>r. Vascular Graft</td>
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### HCT/P Listing - Function Information

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**Institution Name:** National Marrow Donor Program  
**Street Address:** 3061 Broadway Street N.E. Suite 100  
**City:** Minneapolis  
**State:** Minnesota  
**Postal Code:** 55413  
**Country:** United States
When review is complete and correct, Submit to FDA
After Submission…

• Screen will display the information submitted with a Confirmation Number. Record this number or print this screen. This can be used to facilitate communication with FDA if there are questions.

• FDA will send the Reporting Official a validated form.
  – Review information
  – Keep copy of form at your facility
FEI Number: Identification number assigned to facility

Validation date: shows submission is current

FDA uses this information if they choose to inspect the facility
If you named Dr. John Miller as your U.S. Agent, you must send a copy of the validated form to NMDP.

- Electronic copy: lhanley@nmdp.org
- Paper copy: Attn: Lori Hanley
  National Marrow Donor Program
  500 N 5th Street
  Minneapolis, MN 55401

Questions? Contact:
- Lori Hanley: lhanley@nmdp.org