U.S. FDA Establishment Registration: International Centers

Description and Instructions

BE THE MATCH®

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

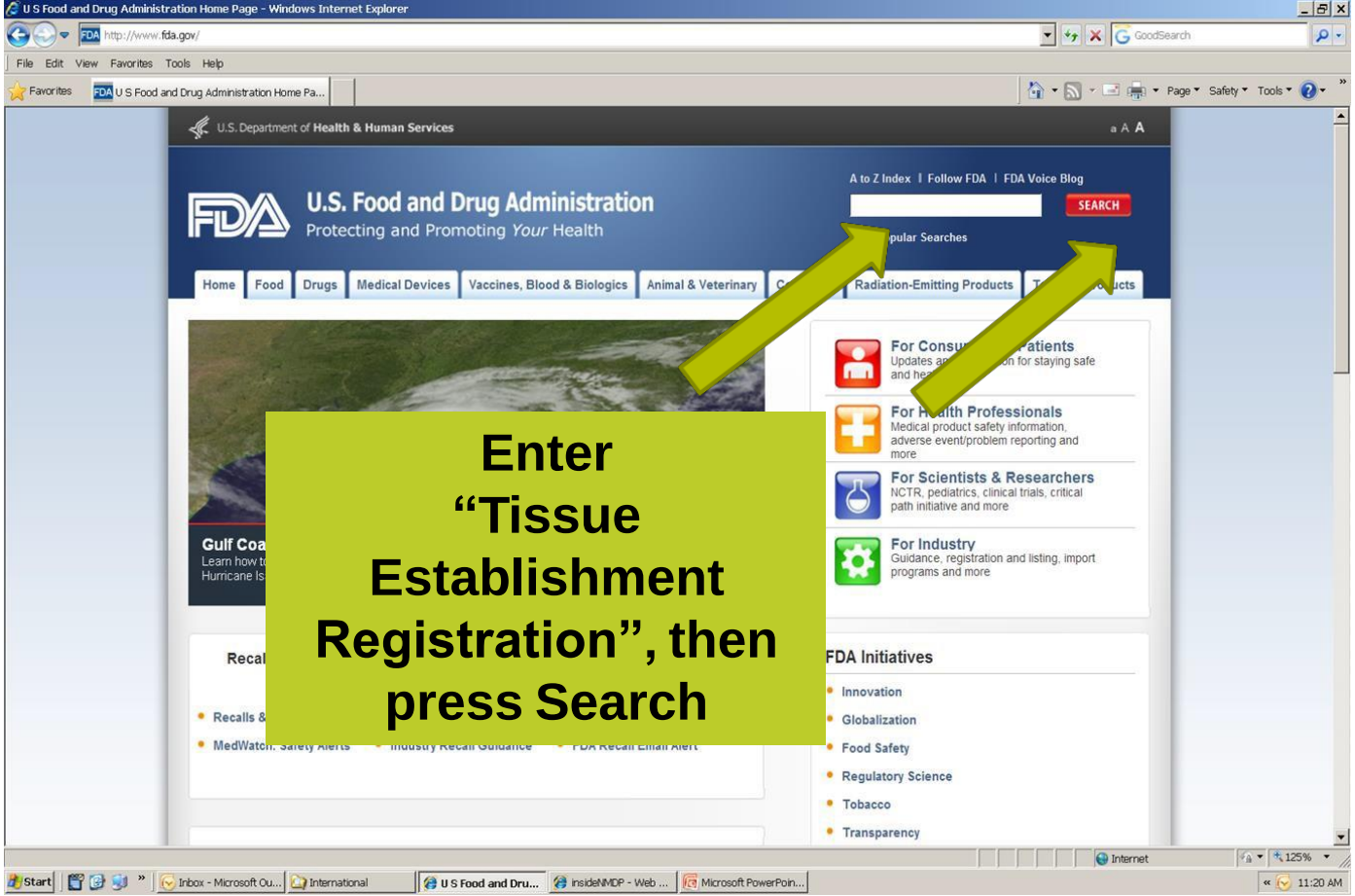
- ***Registration must be renewed every December***

How do I register?

- Electronic form: http://www.fda.gov/
  - 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.


U S Food and Drug Administration Home Page - Windows Internet Explorer
http://www.fda.gov/
File Edit View Favorites Tools Help
Favorites
U S Food and Drug Administration Home Pa...
Page Safety Tools
U.S. Department of Health & Human Services
U.S. Food and Drug Administration
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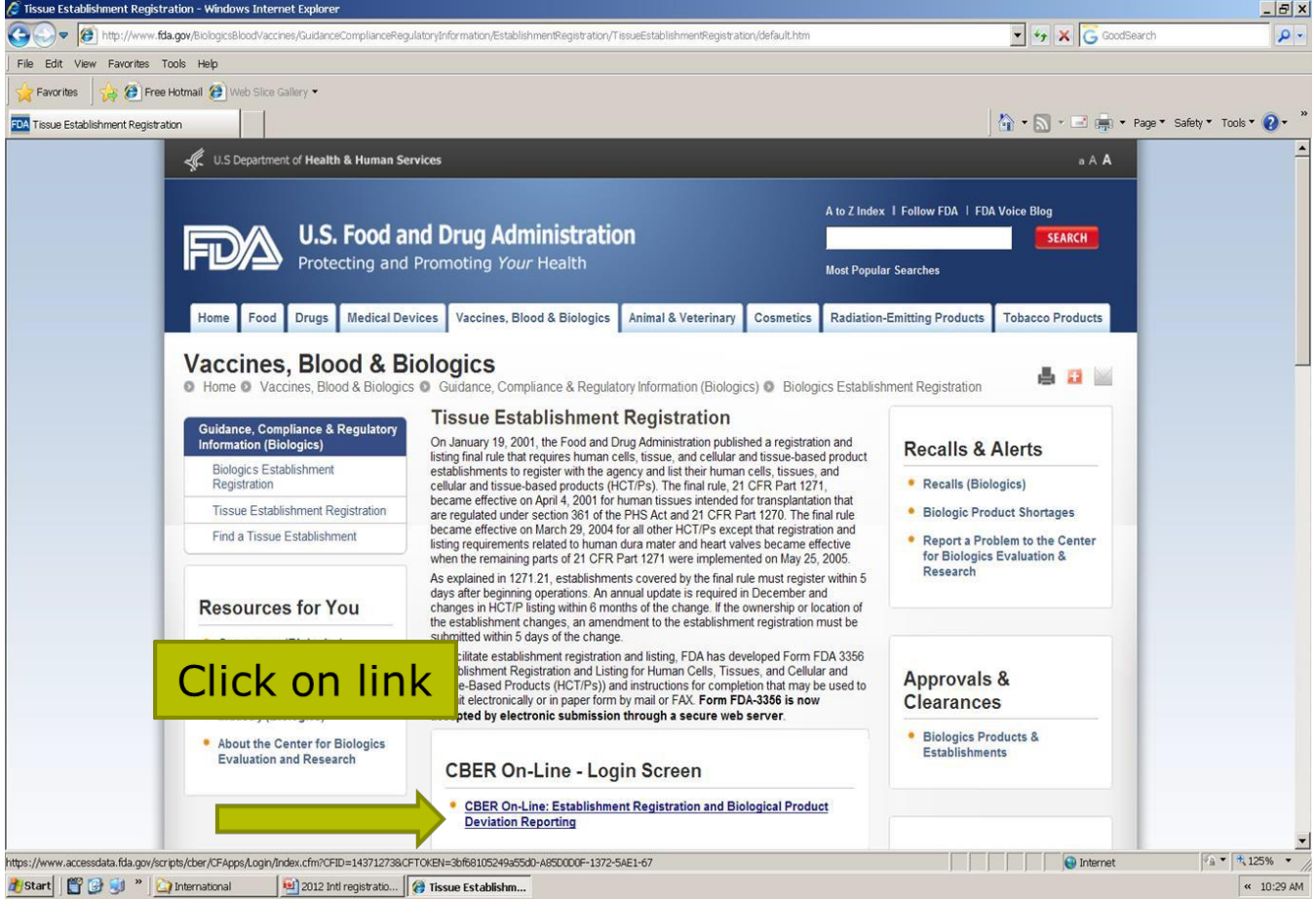
Home
Food
Drugs
Medical Devices
Vaccines, Blood & Biologics
Animal & Veterinary
Radiation-Emitting Products
For Health Professionals
Medical product safety information, adverse event/problem reporting and more
For Scientists & Researchers
NCTR, pediatrics, clinical trials, critical path initiative and more
For Industry
Guidance, registration and listing, import programs and more
FDA Initiatives
Innovation
Globalization
Food Safety
Regulatory Science
Tobacco
Transparency
Enter "Tissue Establishment Registration", then press Search
Start
Inbox - Microsoft Ou...
International
U S Food and Dru...
insideNMDP - Web ...
Microsoft PowerPoin...
Internet
125%
11:20 AM


Tissue Establishment Registration - Windows Internet Explorer
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm
File Edit View Favorites Tools Help
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Tissue Establishment Registration
Page Safety Tools
U.S Department of Health & Human Services
U.S. Food and Drug Administration
Protecting and Promoting Your Health
A to Z Index | Follow FDA | FDA Voice Blog
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Home
Food
Drugs
Medical Devices
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Radiation-Emitting Products
Tobacco Products
Vaccines, Blood & Biologics
Home Vaccines, Blood & Biologics Guidance, Compliance & Regulatory Information (Biologics) Biologics Establishment Registration
Guidance, Compliance & Regulatory Information (Biologics)
Biologics Establishment Registration
Tissue Establishment Registration
Find a Tissue Establishment
Resources for You
About the Center for Biologics Evaluation and Research
Tissue Establishment Registration
On January 19, 2001, the Food and Drug Administration published a registration and listing final rule that requires human cells, tissue, and cellular and tissue-based product establishments to register with the agency and list their human cells, tissues, and cellular and tissue-based products (HCT/Ps). The final rule, 21 CFR Part 1271, became effective on April 4, 2001 for human tissues intended for transplantation that are regulated under section 361 of the PHS Act and 21 CFR Part 1270. The final rule became effective on March 29, 2004 for all other HCT/Ps except that registration and listing requirements related to human dura mater and heart valves became effective when the remaining parts of 21 CFR Part 1271 were implemented on May 25, 2005.
As explained in 1271.21, establishments covered by the final rule must register within 5 days after beginning operations. An annual update is required in December and changes in HCT/P listing within 6 months of the change. If the ownership or location of the establishment changes, an amendment to the establishment registration must be submitted within 5 days of the change.
Click on link
CBER On-Line - Login Screen
CBER On-Line: Establishment Registration and Biological Product Deviation Reporting
Recalls & Alerts
Recalls (Biologics)
Biologic Product Shortages
Report a Problem to the Center for Biologics Evaluation & Research
Approvals & Clearances
Biologics Products & Establishments
https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=14371273&CFTOKEN=3bf68105249a55d0-A85D0D0F-1372-5AE1-67
Internet
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Start
International
2012 Intl registratio...
Tissue Establishm...
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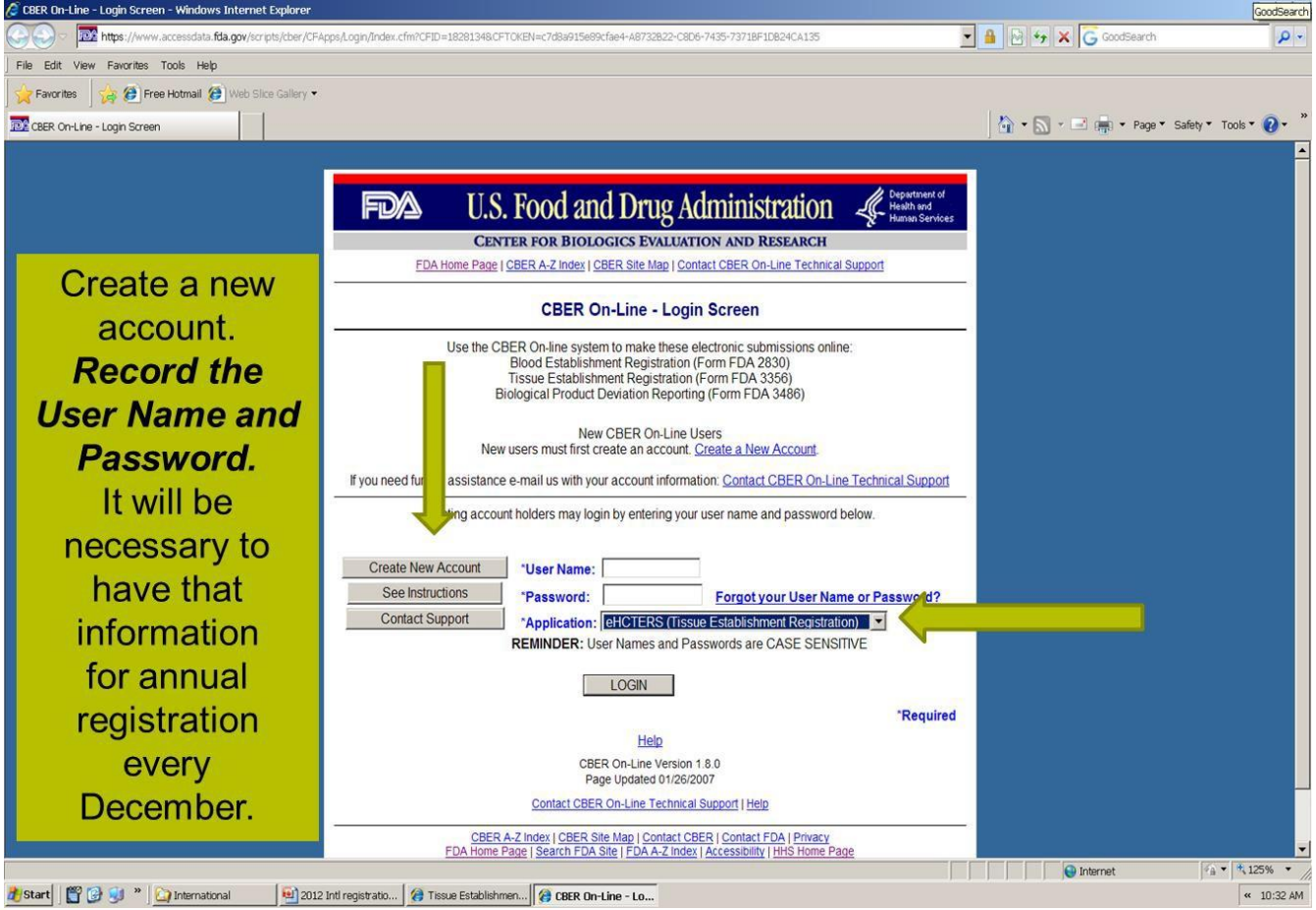
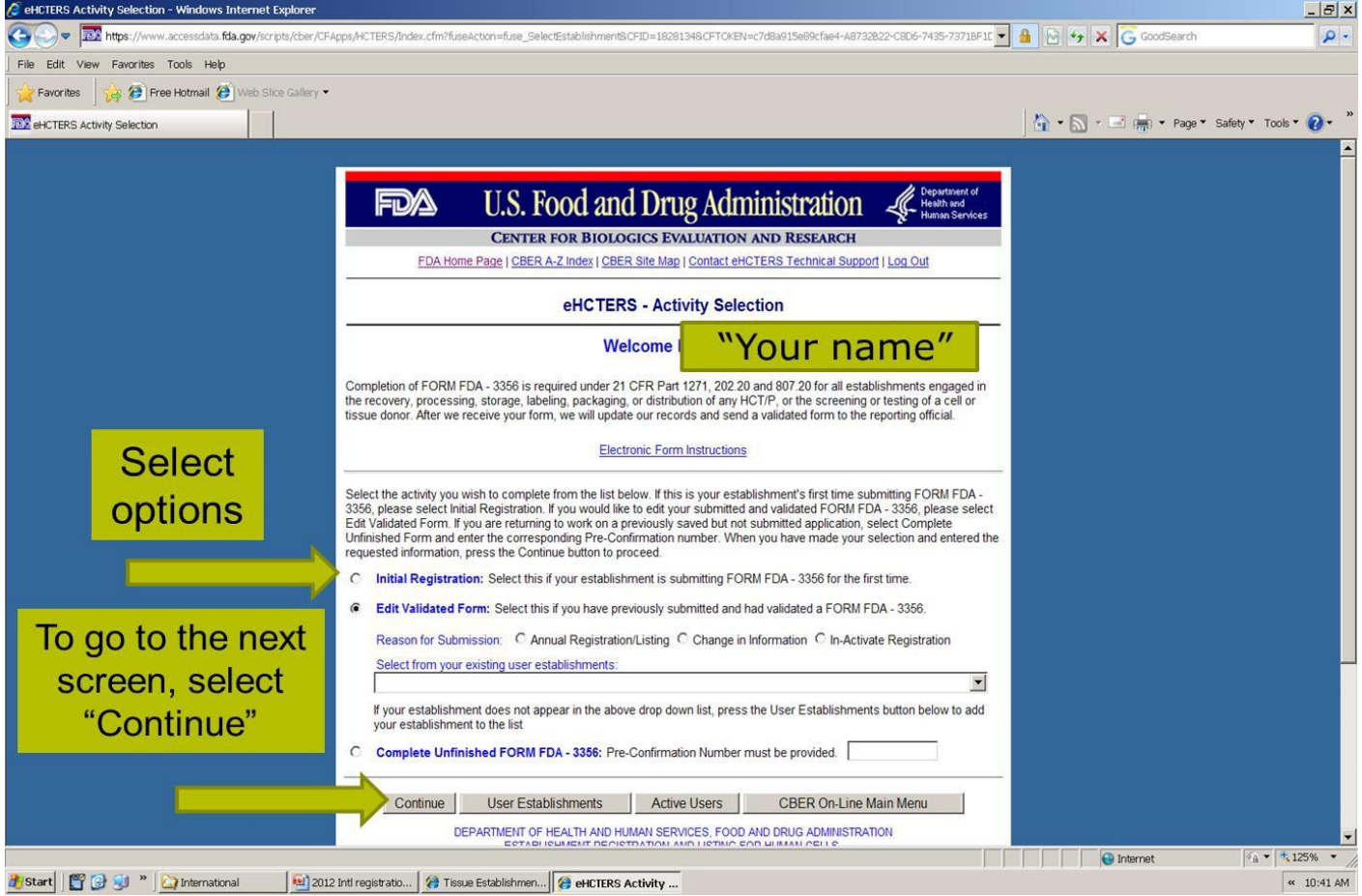
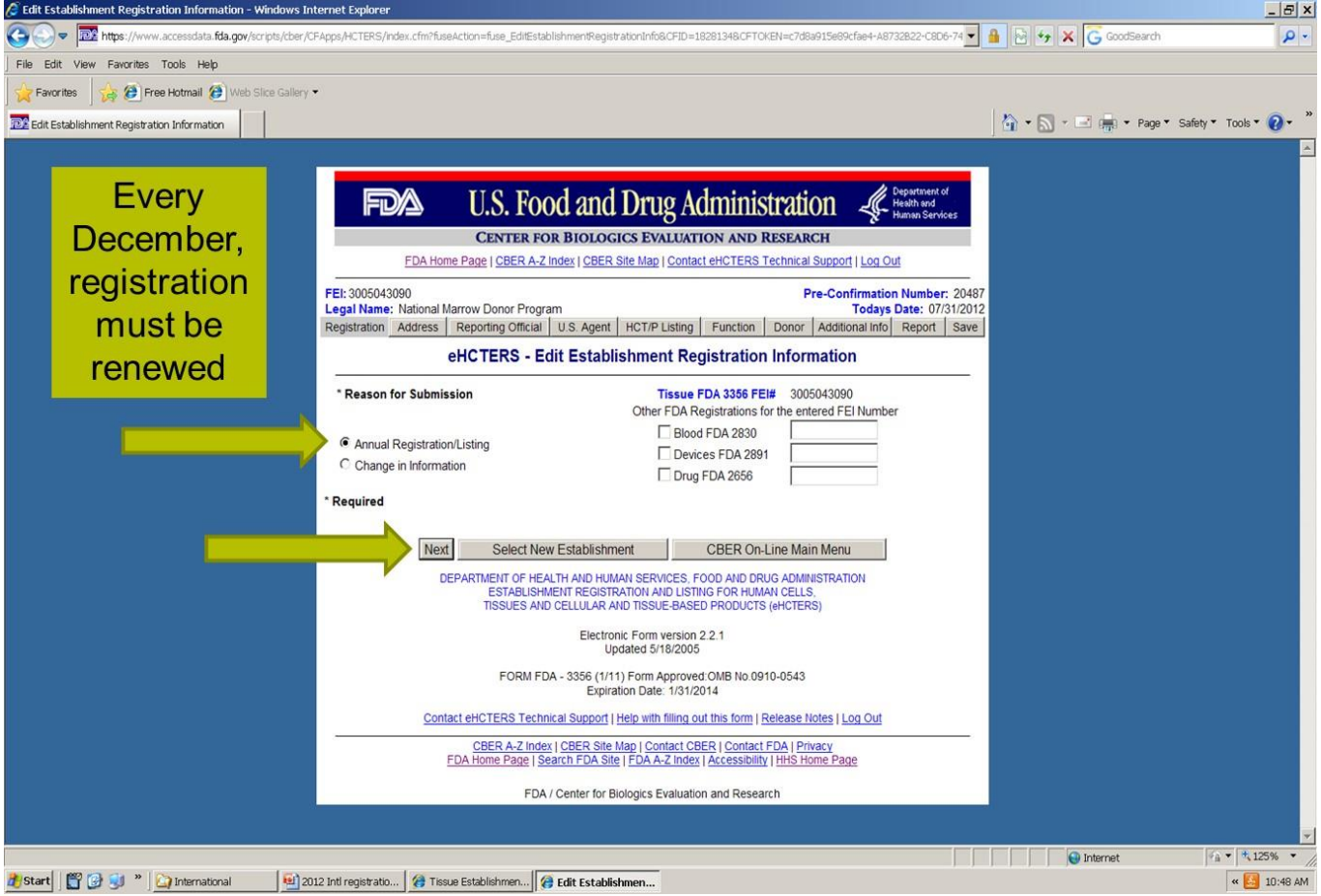
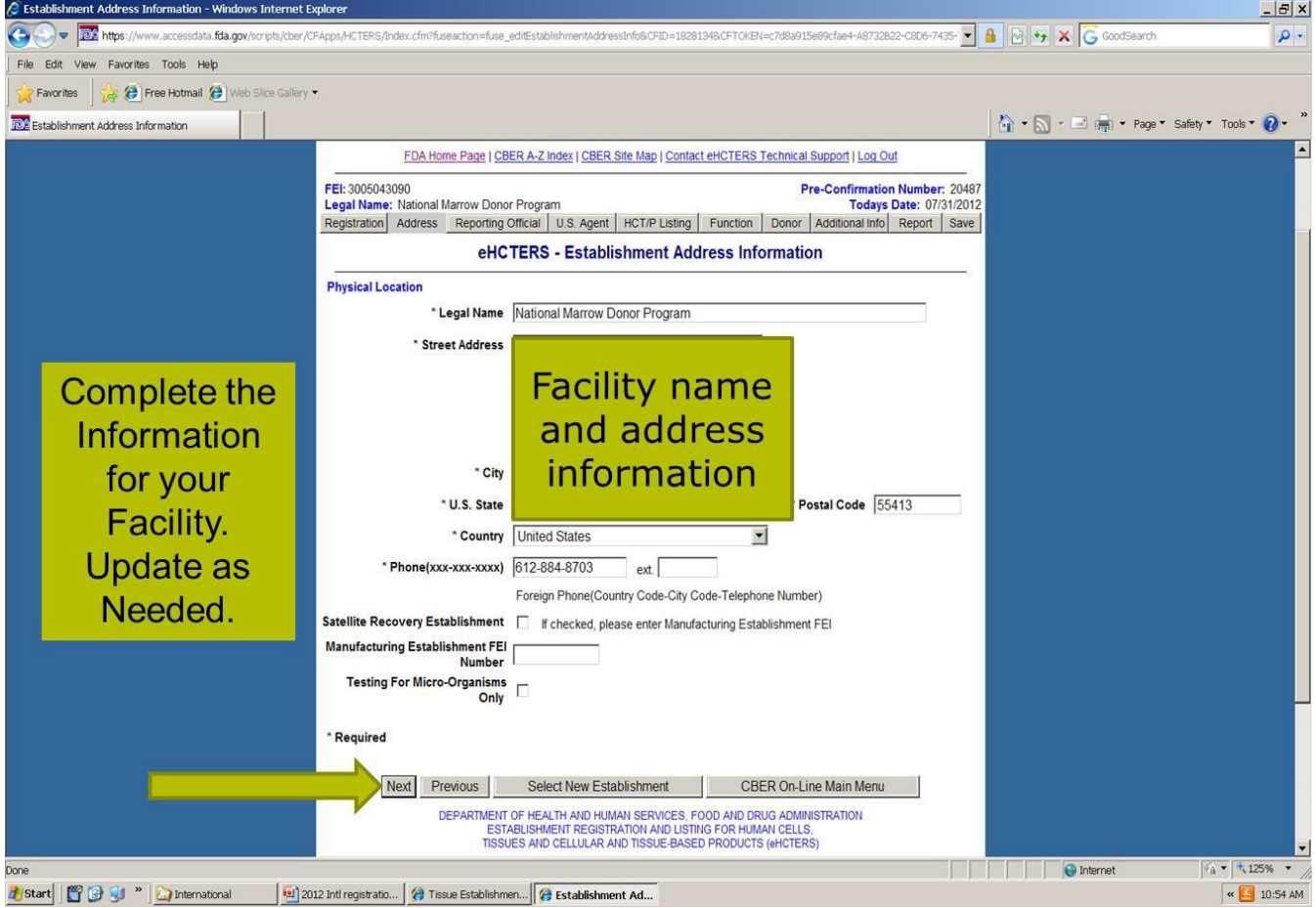

CBER On-Line - Login Screen - Windows Internet Explorer
https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=18281348&CFTOKEN=c7d8a915e89cfae4-A8732B22-C8D6-7435-7371BF1D824CA135
File Edit View Favorites Tools Help
Favorites
Free Hotmail
Web Slice Gallery
CBER On-Line - Login Screen
Page Safety Tools
Create a new account. Record the User Name and Password. It will be necessary to have that information for annual registration every December.
U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FDA Home Page | CBER A-Z Index | CBER Site Map | Contact CBER On-Line Technical Support
CBER On-Line - Login Screen
Use the CBER On-line system to make these electronic submissions online:
Blood Establishment Registration (Form FDA 2830)
Tissue Establishment Registration (Form FDA 3356)
Biological Product Deviation Reporting (Form FDA 3486)
New CBER On-Line Users
New users must first create an account. Create a New Account.
Contact CBER On-Line Technical Support
Create New Account
See Instructions
Contact Support
*User Name:
*Password:
Forgot your User Name or Password?
*Application: eHCTERS (Tissue Establishment Registration)
REMINDER: User Names and Passwords are CASE SENSITIVE
LOGIN
*Required
Help
CBER On-Line Version 1.8.0
Page Updated 01/26/2007
Contact CBER On-Line Technical Support | Help
CBER A-Z Index | CBER Site Map | Contact CBER | Contact FDA | Privacy
FDA Home Page | Search FDA Site | FDA A-Z Index | Accessibility | HHS Home Page
Internet
125%
Start
International
2012 Intl registratio...
Tissue Establishmen...
CBER On-Line - Lo...
10:32 AM

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

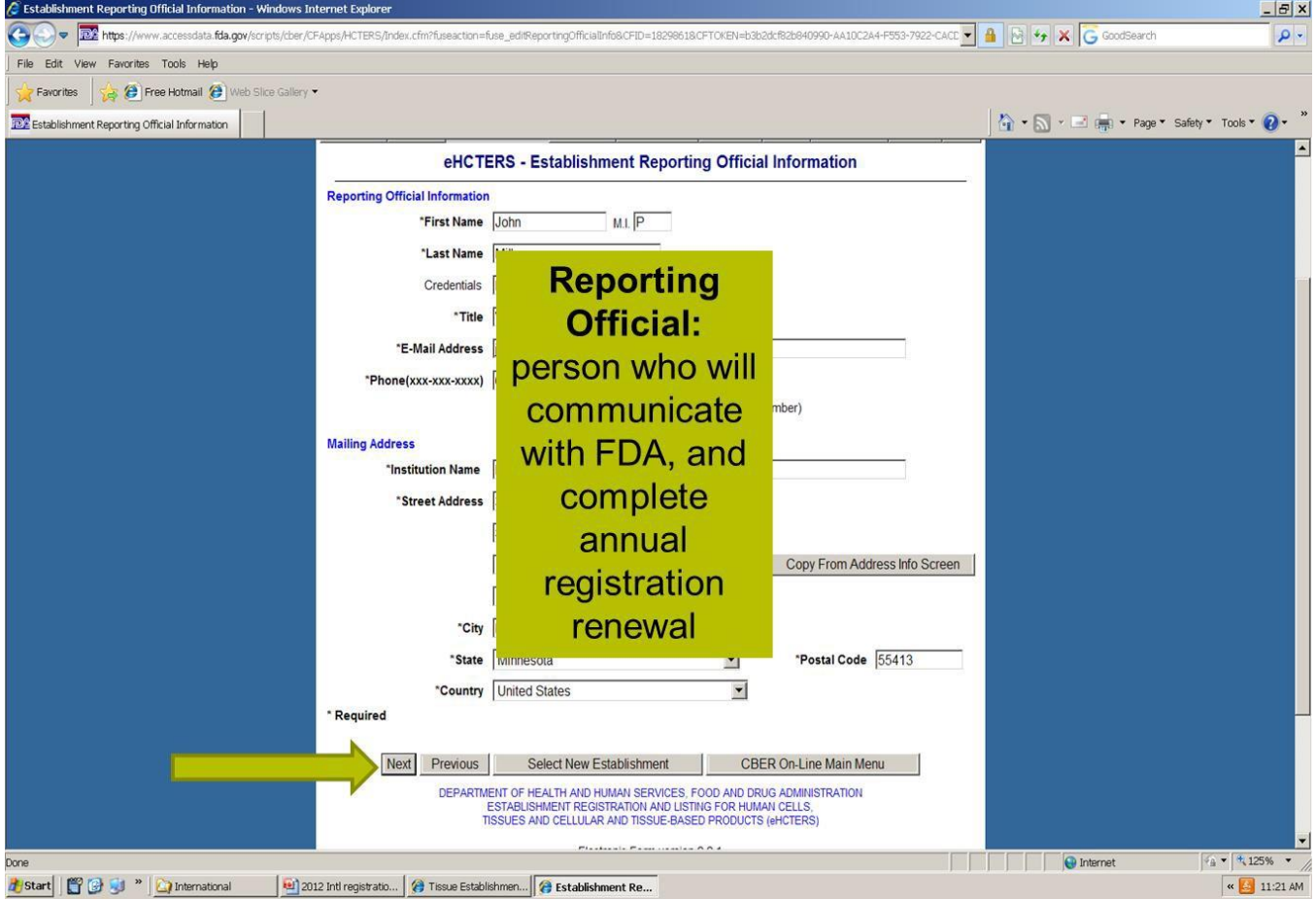

eHCTERS Activity Selection - Windows Internet Explorer
U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FDA Home Page | CBER A-Z Index | CBER Site Map | Contact eHCTERS Technical Support | Log Out
eHCTERS - Activity Selection
Welcome
"Your name"
Completion of FORM FDA - 3356 is required under 21 CFR Part 1271, 202.20 and 807.20 for all establishments engaged in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/P, or the screening or testing of a cell or tissue donor. After we receive your form, we will update our records and send a validated form to the reporting official.
Electronic Form Instructions
Select the activity you wish to complete from the list below. If this is your establishment's first time submitting FORM FDA - 3356, please select Initial Registration. If you would like to edit your submitted and validated FORM FDA - 3356, please select Edit Validated Form. If you are returning to work on a previously saved but not submitted application, select Complete Unfinished Form and enter the corresponding Pre-Confirmation number. When you have made your selection and entered the requested information, press the Continue button to proceed.
Initial Registration: Select this if your establishment is submitting FORM FDA - 3356 for the first time.
Edit Validated Form: Select this if you have previously submitted and had validated a FORM FDA - 3356.
Reason for Submission: Annual Registration/Listing Change in Information In-Activate Registration
Select from your existing user establishments:
If your establishment does not appear in the above drop down list, press the User Establishments button below to add your establishment to the list
Complete Unfinished FORM FDA - 3356: Pre-Confirmation Number must be provided.
Continue
User Establishments
Active Users
CBER On-Line Main Menu
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
Select options
To go to the next screen, select "Continue"


Every December, registration must be renewed
Edit Establishment Registration Information - Windows Internet Explorer
U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FDA Home Page | CBER A-Z Index | CBER Site Map | Contact eHCTERS Technical Support | Log Out
FEI: 3005043090
Legal Name: National Marrow Donor Program
Pre-Confirmation Number: 20487
Todays Date: 07/31/2012
Registration | Address | Reporting Official | U.S. Agent | HCT/P Listing | Function | Donor | Additional Info | Report | Save
eHCTERS - Edit Establishment Registration Information
* Reason for Submission
Annual Registration/Listing
Change in Information
Tissue FDA 3356 FEI# 3005043090
Other FDA Registrations for the entered FEI Number
Blood FDA 2830
Devices FDA 2891
Drug FDA 2656
* Required
Next
Select New Establishment
CBER On-Line Main Menu
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)
Electronic Form version 2.2.1
Updated 5/18/2005
FORM FDA - 3356 (1/11) Form Approved:OMB No.0910-0543
Expiration Date: 1/31/2014
Contact eHCTERS Technical Support | Help with filling out this form | Release Notes | Log Out
CBER A-Z Index | CBER Site Map | Contact CBER | Contact FDA | Privacy
FDA Home Page | Search FDA Site | FDA A-Z Index | Accessibility | HHS Home Page
FDA / Center for Biologics Evaluation and Research


Establishment Address Information - Windows Internet Explorer
FDA Home Page | CBER A-Z Index | CBER Site Map | Contact eHCTERS Technical Support | Log Out
FEI: 3005043090
Legal Name: National Marrow Donor Program
Pre-Confirmation Number: 20487
Todays Date: 07/31/2012
Registration
Address
Reporting Official
U.S. Agent
HCT/P Listing
Function
Donor
Additional Info
Report
Save
eHCTERS - Establishment Address Information
Physical Location
* Legal Name
National Marrow Donor Program
* Street Address
* City
* U.S. State
Postal Code
55413
* Country
United States
* Phone(xxx-xxx-xxxx)
612-884-8703
ext.
Foreign Phone(Country Code-City Code-Telephone Number)
Satellite Recovery Establishment
If checked, please enter Manufacturing Establishment FEI
Manufacturing Establishment FEI Number
Testing For Micro-Organisms Only
* Required
Next
Previous
Select New Establishment
CBER On-Line Main Menu
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)
Complete the Information for your Facility. Update as Needed.
Facility name and address information

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


Establishment Reporting Official Information - Windows Internet Explorer
eHCTERS - Establishment Reporting Official Information
Reporting Official Information
*First Name
John
M.I.
P
*Last Name
Credentials
*Title
*E-Mail Address
*Phone(xxx-xxx-xxxx)
Mailing Address
*Institution Name
*Street Address
Copy From Address Info Screen
*City
*State
Minnesota
*Postal Code
55413
*Country
United States
* Required
Next
Previous
Select New Establishment
CBER On-Line Main Menu
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)
Reporting Official:
person who will communicate with FDA, and complete annual registration renewal

U.S. Agent

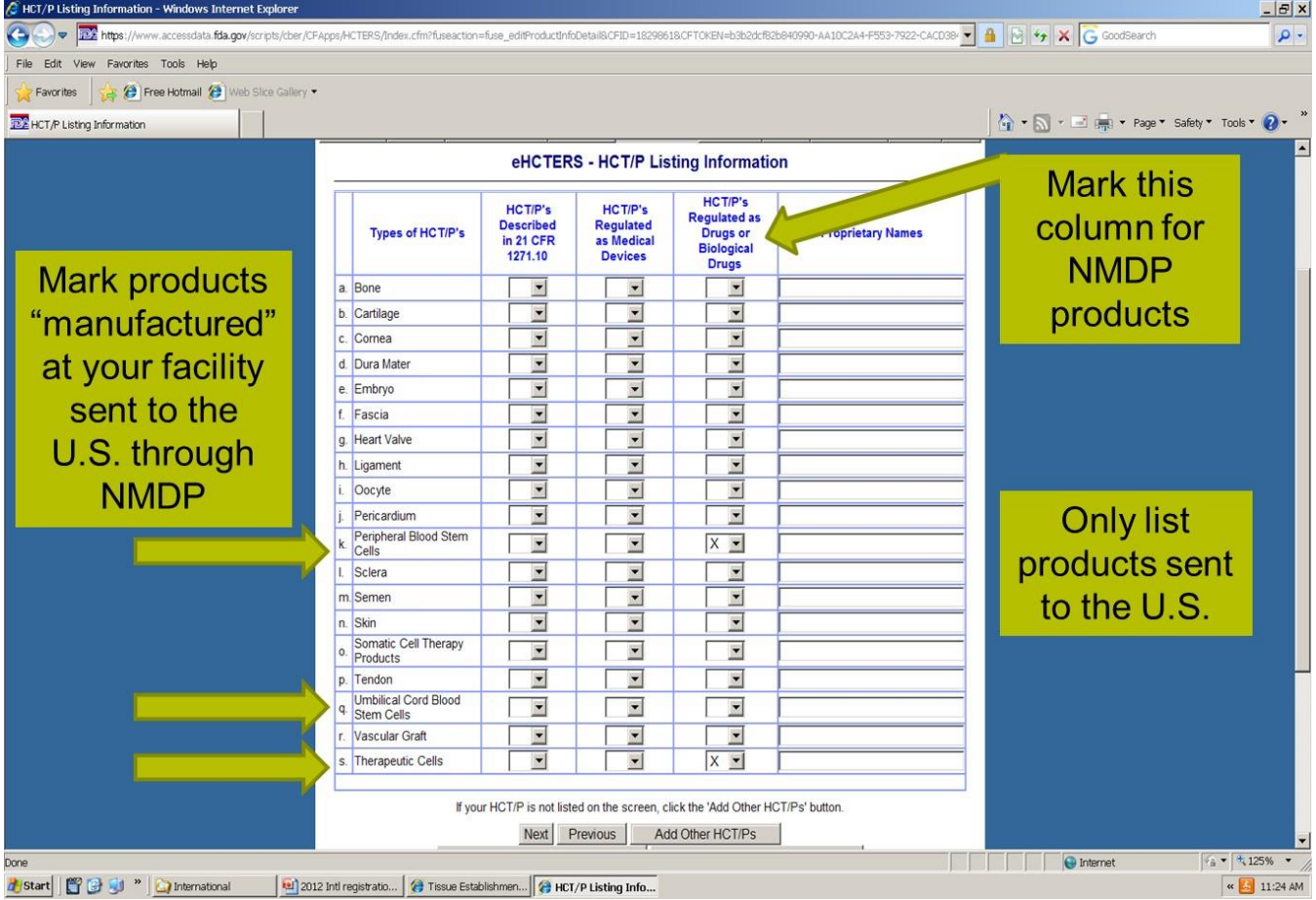
- Non-U.S. facilities must name a U.S. Agent
- This person serves as a U.S. contact for your facility
  - if U.S. Customs has a question about a product coming into the U.S., or
  - if the FDA would need to inspect a facility

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:

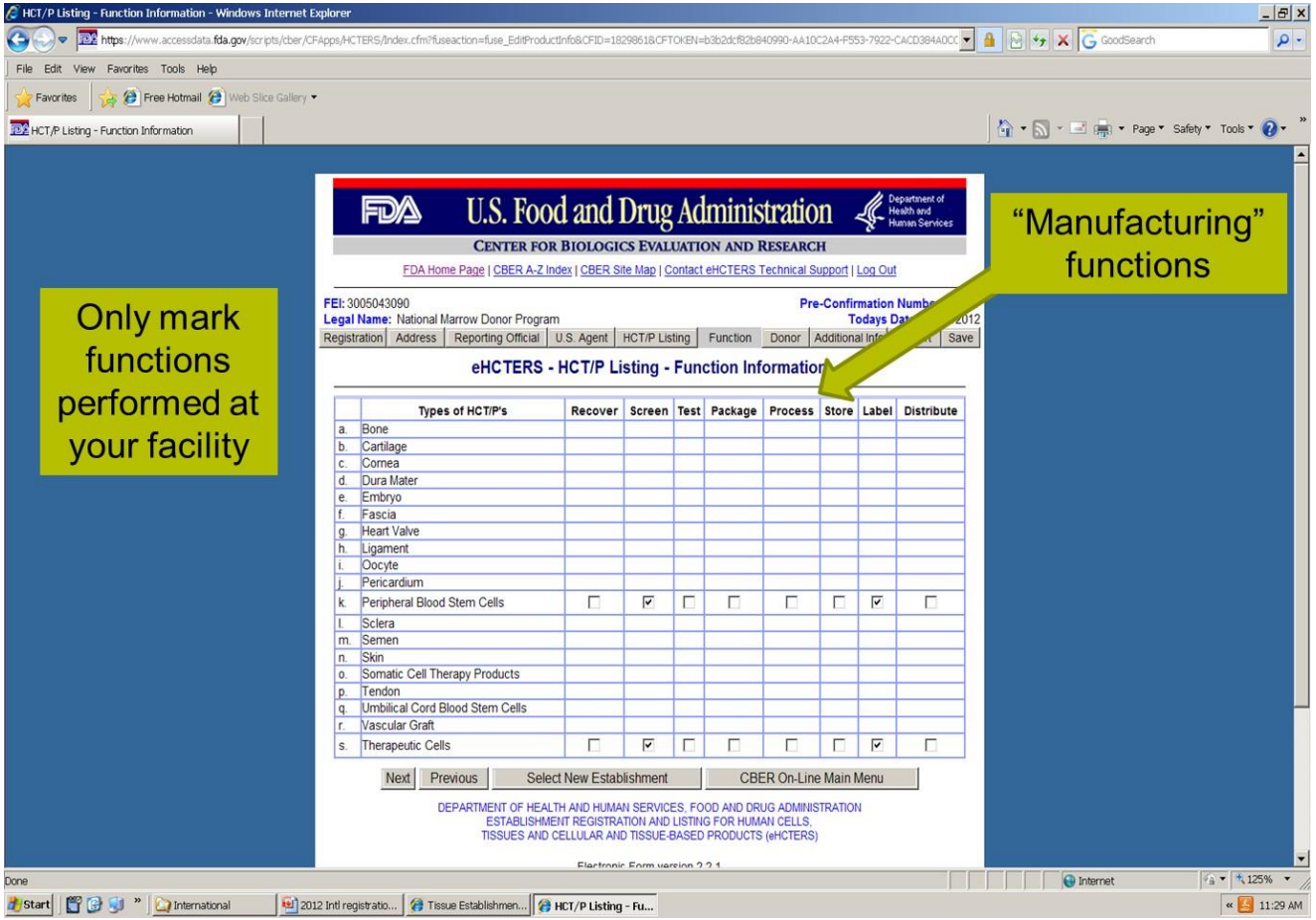
  John Miller, M.D., Ph.D.
  National Marrow Donor Program
  500 North 5th Street
  Minneapolis, MN 55401 USA
  jmiller5@nmdp.org
  1-763-406-5800

- If your products are also sent via direct arrangements with a transplant center, you may **NOT** use Dr. Miller as your U.S. Agent.

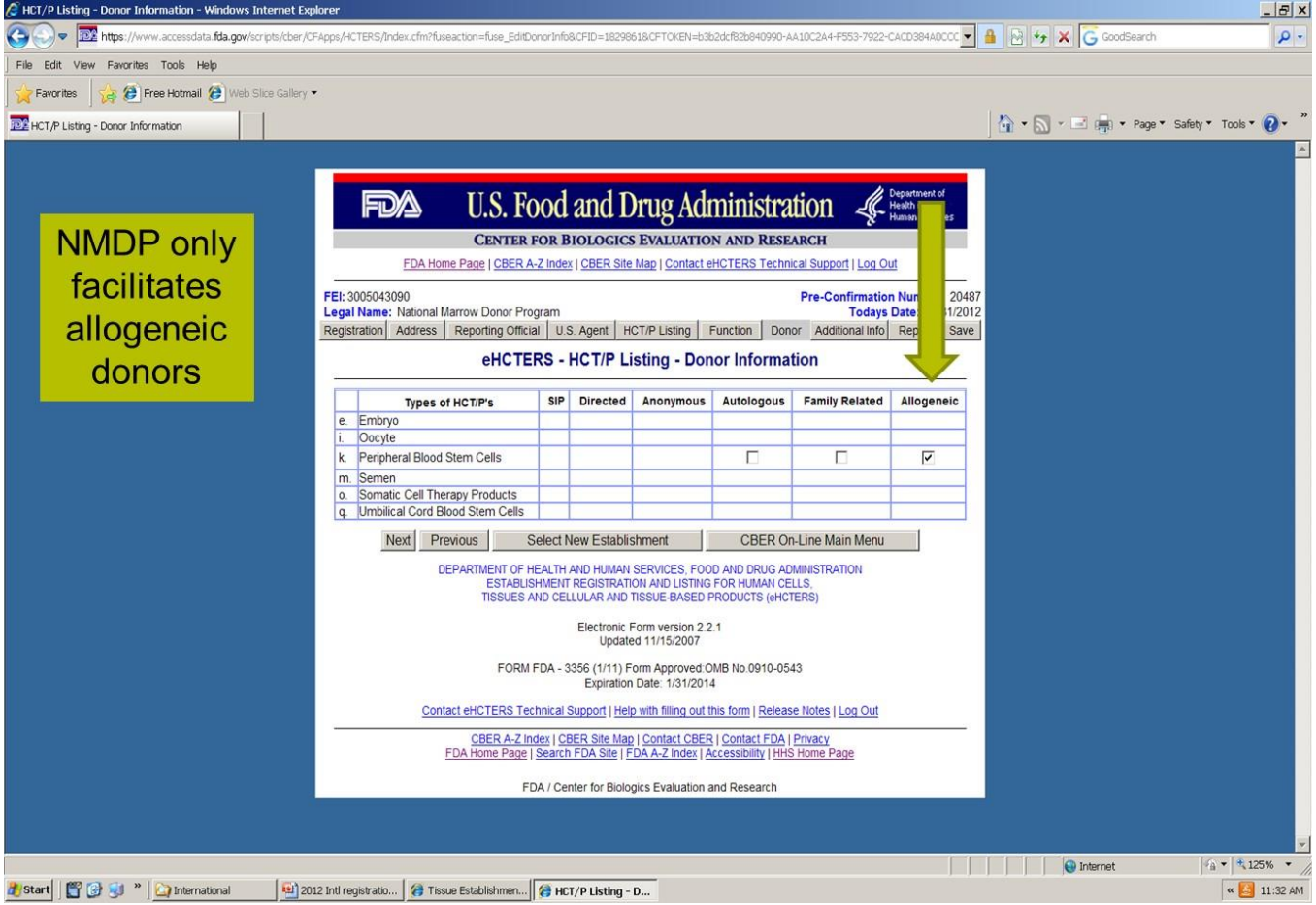

HCT/P Listing Information - Windows Internet Explorer
eHCTERS - HCT/P Listing Information
Types of HCT/P's
HCT/P's Described in 21 CFR 1271.10
HCT/P's Regulated as Medical Devices
HCT/P's Regulated as Drugs or Biological Drugs
Proprietary Names
a. Bone
b. Cartilage
c. Cornea
d. Dura Mater
e. Embryo
f. Fascia
g. Heart Valve
h. Ligament
i. Oocyte
j. Pericardium
k. Peripheral Blood Stem Cells
l. Sclera
m. Semen
n. Skin
o. Somatic Cell Therapy Products
p. Tendon
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
s. Therapeutic Cells
If your HCT/P is not listed on the screen, click the 'Add Other HCT/Ps' button.
Next
Previous
Add Other HCT/Ps
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.

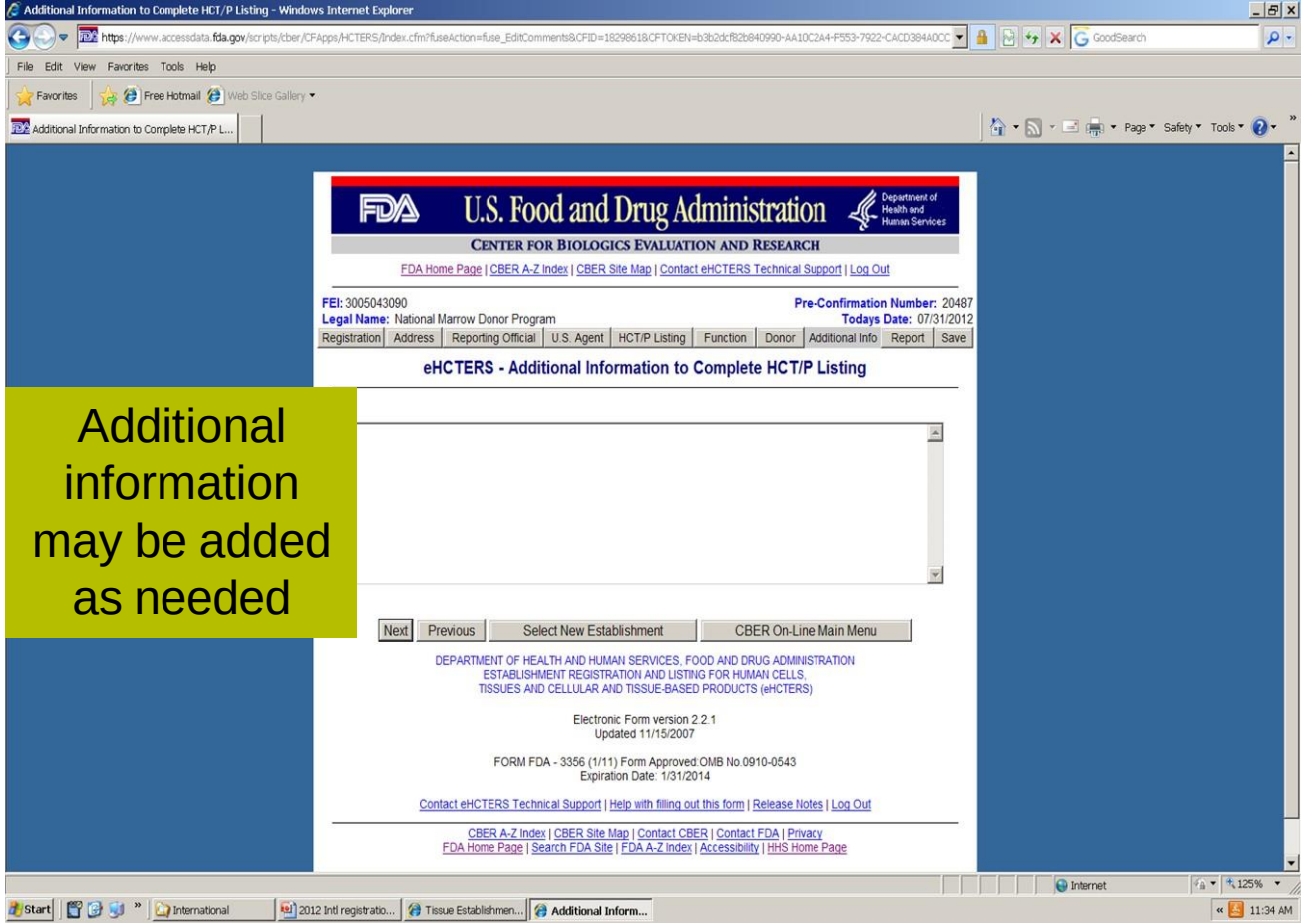
What is “Manufacturing?”

- 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)

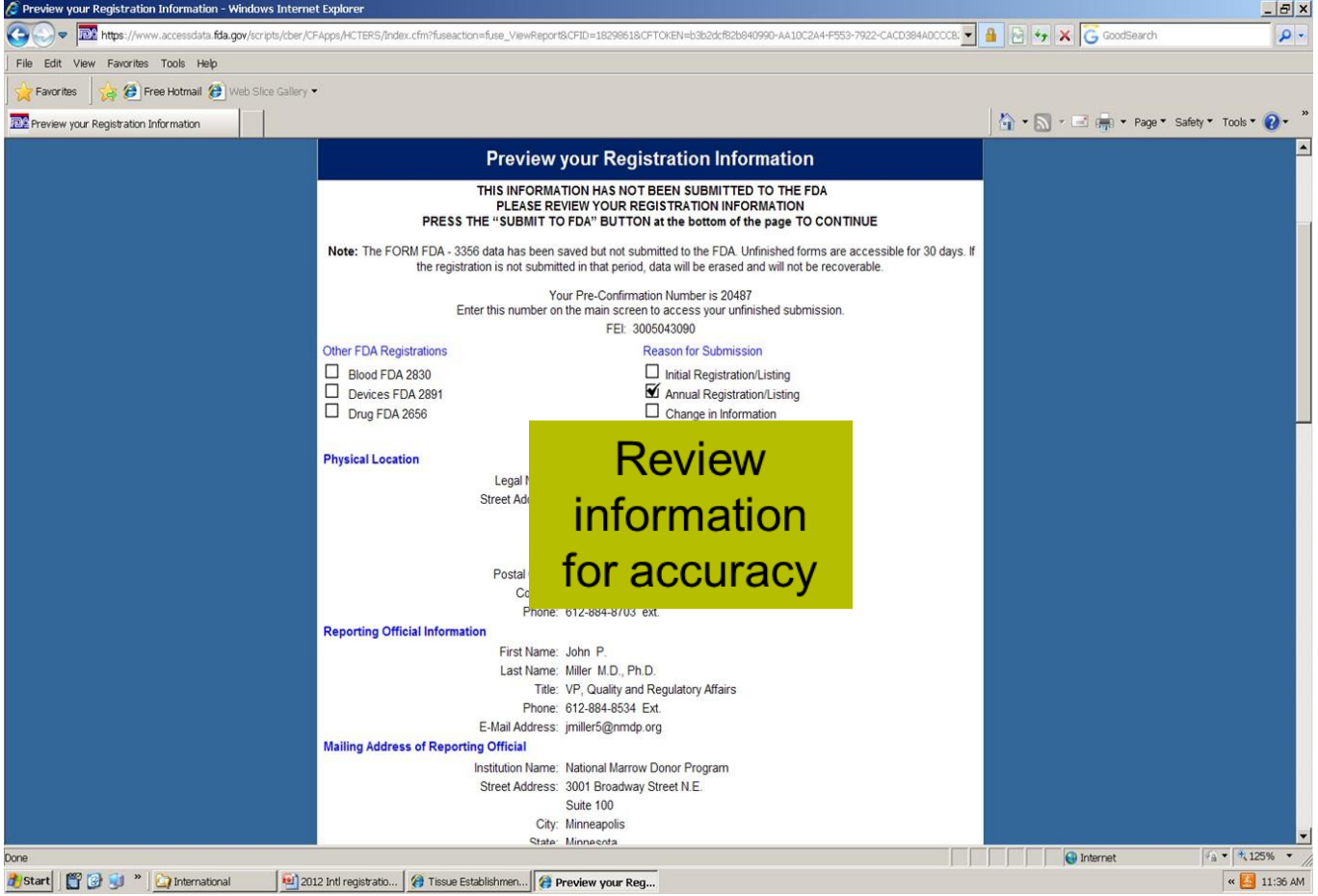

HCT/P Listing - Function Information - Windows Internet Explorer
U.S. Food and Drug Administration
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FDA Home Page | CBER A-Z Index | CBER Site Map | Contact eHCTERS Technical Support | Log Out
FEI: 3005043090
Legal Name: National Marrow Donor Program
Registration | Address | Reporting Official | U.S. Agent | HCT/P Listing | Function | Donor | Additional Info | Save
eHCTERS - HCT/P Listing - Function Information
Types of HCT/P's | Recover | Screen | Test | Package | Process | Store | Label | Distribute
a. Bone
b. Cartilage
c. Cornea
d. Dura Mater
e. Embryo
f. Fascia
g. Heart Valve
h. Ligament
i. Oocyte
j. Pericardium
k. Peripheral Blood Stem Cells
l. Sclera
m. Semen
n. Skin
o. Somatic Cell Therapy Products
p. Tendon
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
s. Therapeutic Cells
Next | Previous | Select New Establishment | CBER On-Line Main Menu
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)
Only mark functions performed at your facility
"Manufacturing" functions

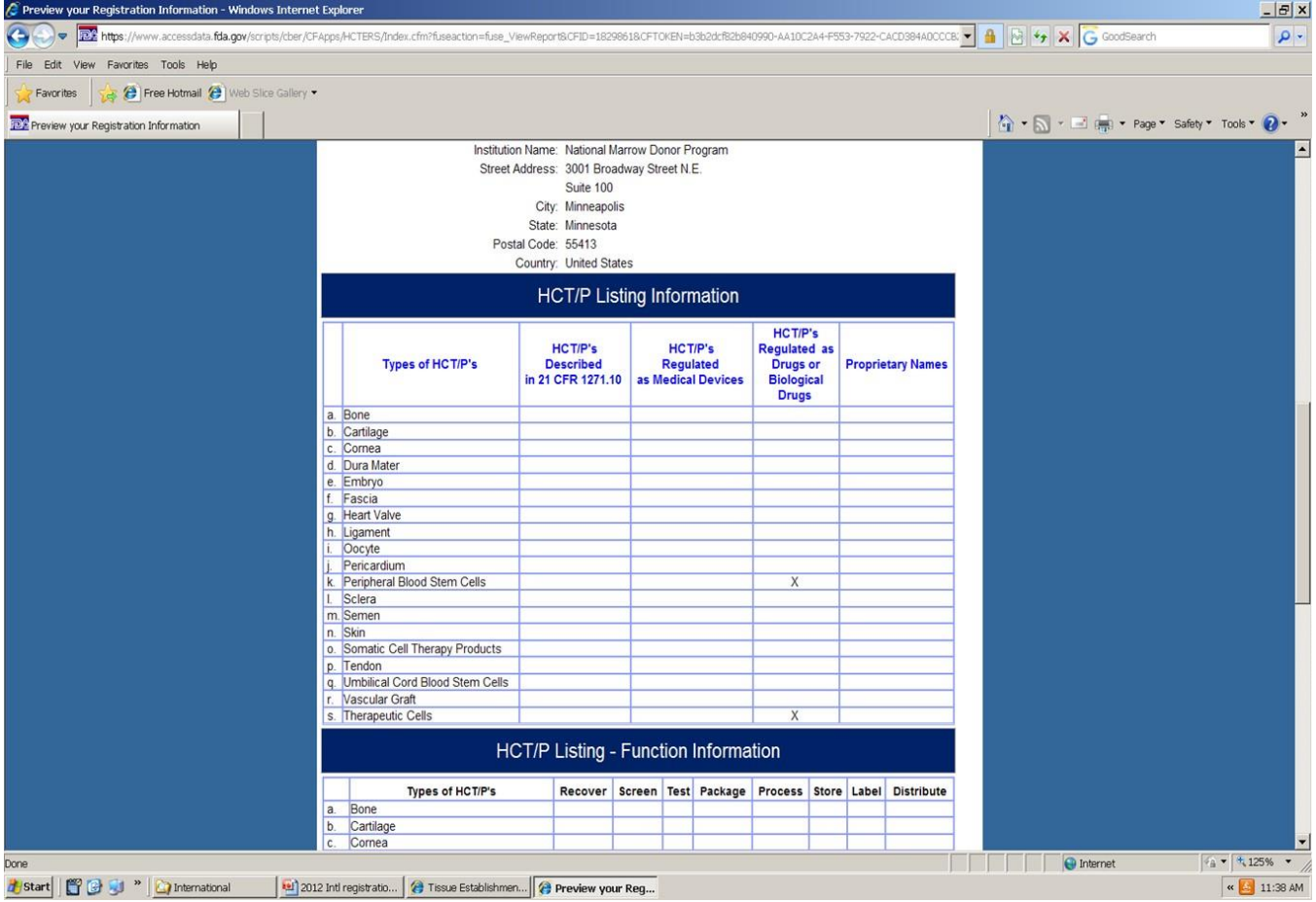
NMDP only facilitates allogeneic donors





Additional information may be added as needed


Preview your Registration Information - Windows Internet Explorer
Preview your Registration Information
THIS INFORMATION HAS NOT BEEN SUBMITTED TO THE FDA
PLEASE REVIEW YOUR REGISTRATION INFORMATION
PRESS THE "SUBMIT TO FDA" BUTTON at the bottom of the page TO CONTINUE
Note: The FORM FDA - 3356 data has been saved but not submitted to the FDA. Unfinished forms are accessible for 30 days. If the registration is not submitted in that period, data will be erased and will not be recoverable.
Your Pre-Confirmation Number is 20487
Enter this number on the main screen to access your unfinished submission.
FEI: 3005043090
Other FDA Registrations
Blood FDA 2830
Devices FDA 2891
Drug FDA 2656
Reason for Submission
Initial Registration/Listing
Annual Registration/Listing
Change in Information
Physical Location
Review information for accuracy
Phone: 612-884-8703 ext.
Reporting Official Information
First Name: John P.
Last Name: Miller M.D., Ph.D.
Title: VP, Quality and Regulatory Affairs
Phone: 612-884-8534 Ext.
E-Mail Address: jmiller5@nmdp.org
Mailing Address of Reporting Official
Institution Name: National Marrow Donor Program
Street Address: 3001 Broadway Street N.E.
Suite 100
City: Minneapolis


Preview your Registration Information - Windows Internet Explorer
https://www.accessdata.fda.gov/scripts/cber/CFApps/HCTERS/Index.cfm?fuseaction=fuse_ViewReport&CFID=18298618&CFTOKEN=b3b2dcf82b840990-AA10C2A4-F553-7922-CACD384A0CCCB
File Edit View Favorites Tools Help
Favorites
Free Hotmail
Web Slice Gallery
Preview your Registration Information
Page
Safety
Tools
Institution Name: National Marrow Donor Program
Street Address: 3001 Broadway Street N.E.
Suite 100
City: Minneapolis
State: Minnesota
Postal Code: 55413
Country: United States
HCT/P Listing Information
Types of HCT/P's
HCT/P's Described in 21 CFR 1271.10
HCT/P's Regulated as Medical Devices
HCT/P's Regulated as Drugs or Biological Drugs
Proprietary Names
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h. Ligament
i. Oocyte
j. Pericardium
k. Peripheral Blood Stem Cells X
l. Sclera
m. Semen
n. Skin
o. Somatic Cell Therapy Products
p. Tendon
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
s. Therapeutic Cells X
HCT/P Listing - Function Information
Types of HCT/P's
Recover
Screen
Test
Package
Process
Store
Label
Distribute
a. Bone
b. Cartilage
c. Cornea
Done
Internet
125%
Start
International
2012 Intl registratio...
Tissue Establishmen...
Preview your Reg...
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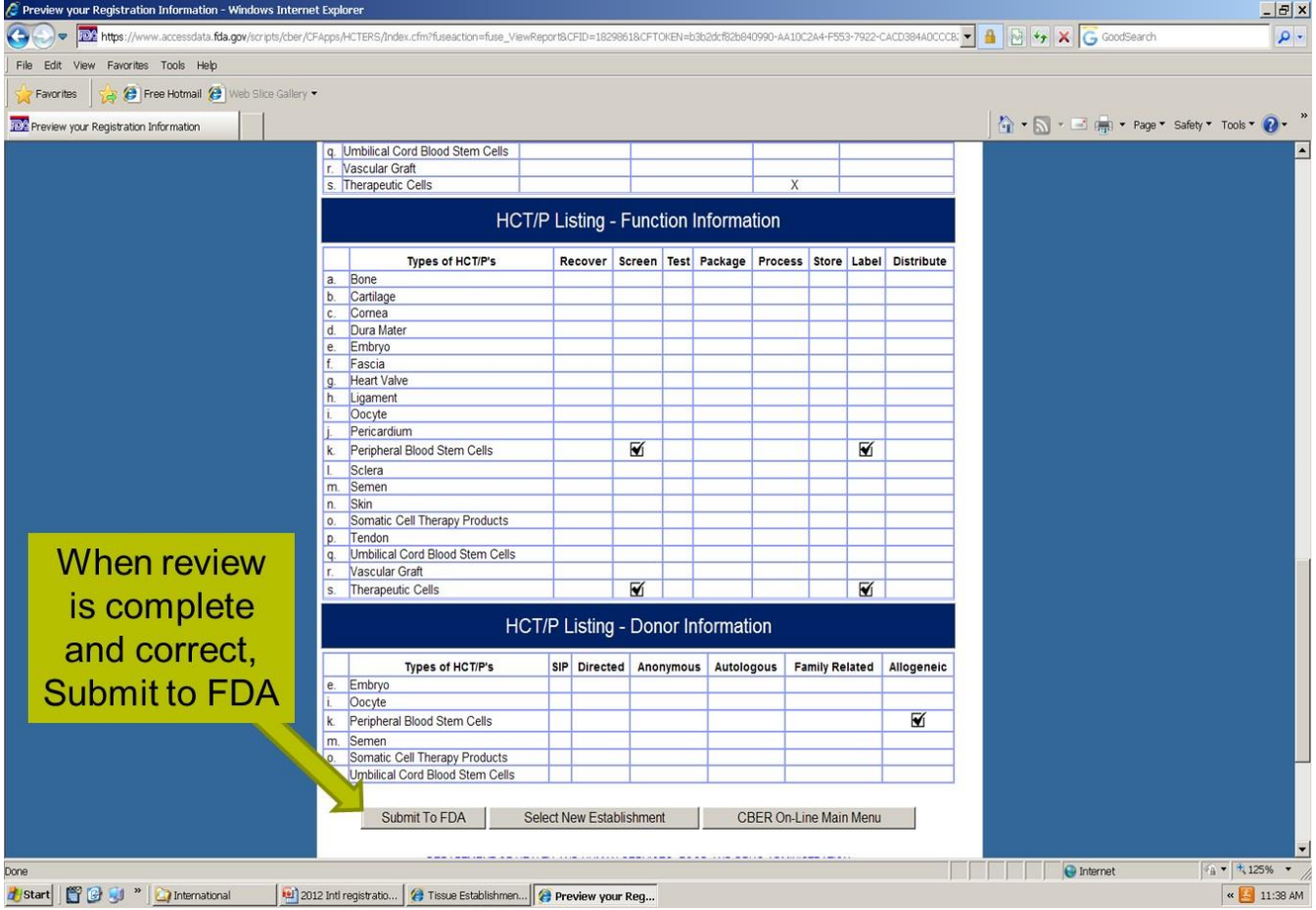
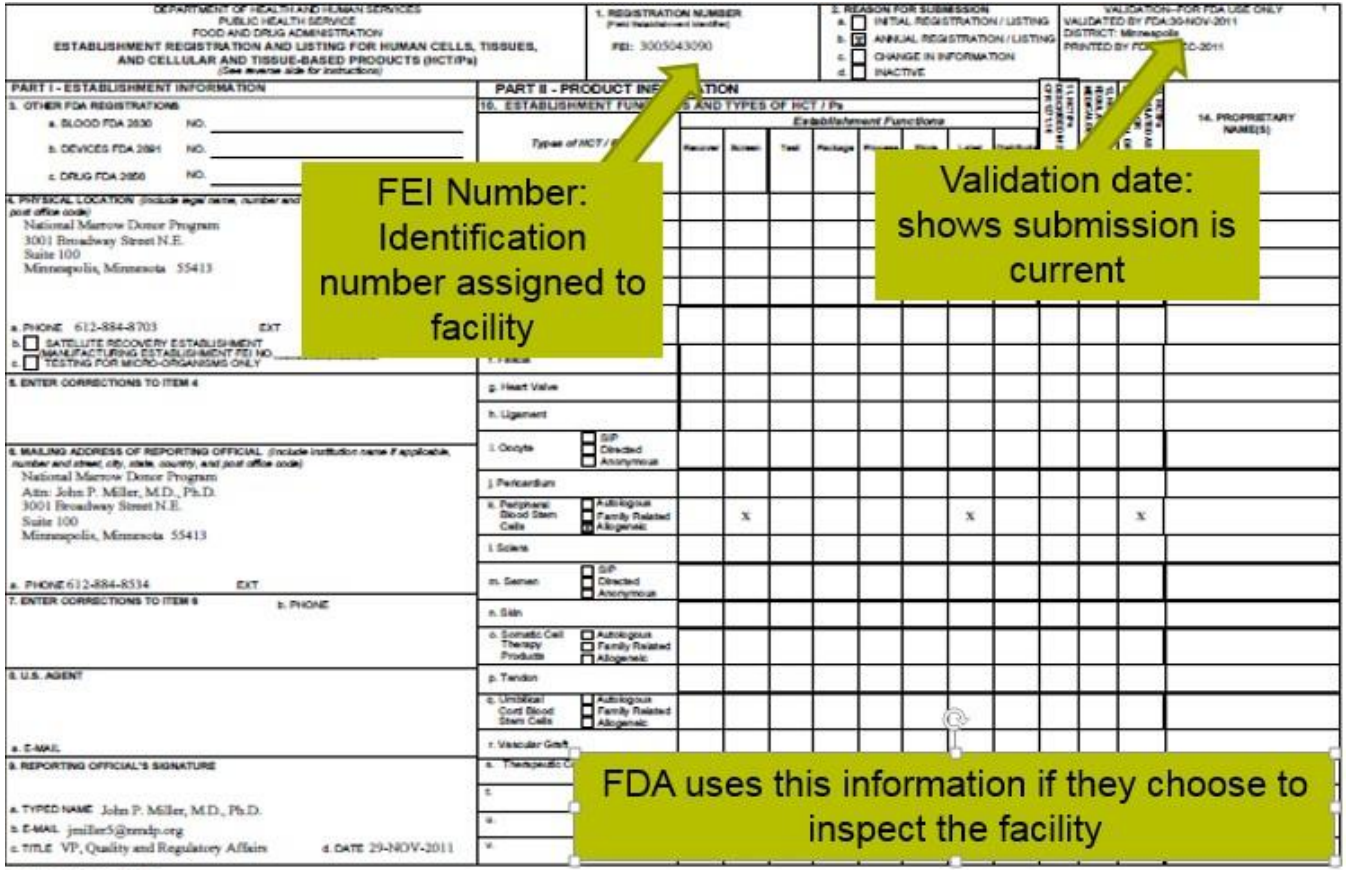

Preview your Registration Information - Windows Internet Explorer
https://www.accessdata.fda.gov/scripts/cber/CFApps/HCTERS/Index.cfm?fuseaction=fuse_ViewReport&CFID=18298618&CFTOKEN=b3b2dcf82b840990-AA10C2A4-F553-7922-CACD384A0CCCB
File Edit View Favorites Tools Help
Favorites
Free Hotmail
Web Slice Gallery
Preview your Registration Information
Page Safety Tools
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
s. Therapeutic Cells X
HCT/P Listing - Function Information
Types of HCT/P's | Recover | Screen | Test | Package | Process | Store | Label | Distribute
a. Bone
b. Cartilage
c. Cornea
d. Dura Mater
e. Embryo
f. Fascia
g. Heart Valve
h. Ligament
i. Oocyte
j. Pericardium
k. Peripheral Blood Stem Cells ☑ ☑
l. Sclera
m. Semen
n. Skin
o. Somatic Cell Therapy Products
p. Tendon
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
s. Therapeutic Cells ☑ ☑
When review is complete and correct, Submit to FDA
HCT/P Listing - Donor Information
Types of HCT/P's | SIP | Directed | Anonymous | Autologous | Family Related | Allogeneic
e. Embryo
i. Oocyte
k. Peripheral Blood Stem Cells ☑
m. Semen
o. Somatic Cell Therapy Products
Umbilical Cord Blood Stem Cells
Submit To FDA
Select New Establishment
CBER On-Line Main Menu
Done
Internet
125%
Start
International
2012 Intl registratio...
Tissue Establishmen...
Preview your Reg...
11:38 AM

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


DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)
1. REGISTRATION NUMBER
FEI: 3005043090
2. REASON FOR SUBMISSION
b. ANNUAL REGISTRATION / LISTING
VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:30-NOV-2011
PART I - ESTABLISHMENT INFORMATION
3. OTHER FDA REGISTRATIONS
4. PHYSICAL LOCATION
National Marrow Donor Program
3001 Broadway Street N.E.
Suite 100
Minneapolis, Minnesota 55413
a. PHONE 612-884-8703
5. ENTER CORRECTIONS TO ITEM 4
6. MAILING ADDRESS OF REPORTING OFFICIAL
National Marrow Donor Program
Attn: John P. Miller, M.D., Ph.D.
3001 Broadway Street N.E.
Suite 100
Minneapolis, Minnesota 55413
a. PHONE 612-884-8534
7. ENTER CORRECTIONS TO ITEM 6
8. U.S. AGENT
9. REPORTING OFFICIAL'S SIGNATURE
a. TYPED NAME John P. Miller, M.D., Ph.D.
b. E-MAIL jmiller5@nmdp.org
c. TITLE VP, Quality and Regulatory Affairs
d. DATE 29-NOV-2011
PART II - PRODUCT INFORMATION
10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps
Establishment Functions
Types of HCT / Ps
14. PROPRIETARY NAME(S)
g. Heart Valve
h. Ligament
i. Oocyte
j. Pericardium
k. Peripheral Blood Stem Cells
l. Sclera
m. Semen
n. Skin
o. Somatic Cell Therapy Products
p. Tendon
q. Umbilical Cord Blood Stem Cells
r. Vascular Graft
FORM FDA 3356 (4/08)
FEI Number: Identification number assigned to facility
Validation date: shows submission is current
FDA uses this information if they choose to inspect the facility

After Submission…

If you named Dr. John Miller as your U.S. Agent, you must send an electronic copy of the validated form to NMDP at regulatory@nmdp.org.

Questions? Contact Regulatory Affairs: regulatory@nmdp.org