

# BER Instructions for Completing the Electronic Blood Establishment Registration and Product Listing Form

The FDA requires all blood establishments that collect, manufacture, prepare, store under controlled conditions for further distribution, or process blood and blood products to register under Title 21, CFR, Part 607. Hospital Transfusion Services certified under the Medicare program are exempt from registration (see 21 CFR 607.65(f)).

Establishments that perform certain manufacturing steps are considered to be Hospital Blood Banks, which are required to register. See instructions for Item 10.2 for these manufacturing steps.

The Paperwork Reduction Act Statement is at the end of these instructions.

Please review all pre-populated data for accuracy and completeness. Correct any incorrect items as you navigate through the application.

Note the following: **YOU MUST NOTIFY FDA WITHIN 5 DAYS IF YOU CHANGE LOCATION.**

The Electronic Blood Establishment Registration and Product Listing system is referred to as eBER. The blood establishment and product listing process is referred to as registration and listing. To view a list of frequently asked questions and their answers, please visit the [eBER FAQ](#) page.

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### **General Instructions:**

- Complete a separate eBER record for each establishment.
- Complete all sections. The U.S. Agent section applies only to non-U.S. military blood establishments.
- Click the associated links located at the bottom of each page for:
  - **Log Out** - returns you to the CBER On Line Log In page.
  - **Help with filling out this form** - provides on-line instructions for completing the form.
  - **Contact CBER** - opens a web email form for users to send comments and questions to CBER.
  - **Release Notes** - displays latest release notes for the eBER system.
  - **FAQ** - displays a collection of frequently asked questions and answers regarding the eBER system.
- Enter dates as month/day/year (e.g. December 1, 2001 = 12/01/2001).
- Enter US phone numbers as 10 digit numbers (area code + phone number) separated by dashes. Example: 123-555-1212
- Enter US zip codes as five digit zip code + four digit extension separated by a dash. Example: 12345-1234. If you do not know the four-digit extension, just enter the five-digit zip code.
- All fields marked with an asterisk (\*) and written in blue are required fields. You must complete these fields before you submit your registration to CBER.
- When available, please provide the reporting official's (and US Agent's) email address to facilitate our contacting you for additional information when necessary.
- DO NOT use this form to report biological product deviations, fatalities, or adverse events.
- We recommend you print these general instructions for reference when completing the electronic form.

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### **Navigation**

There is a continue button on nearly every page of eBER. Clicking this button will take you to the next page of the application.

Use the **TAB** key or mouse for screen navigation. When you press the **Enter** key, the system will check the page for required fields and valid information as if you had hit the Continue button on the bottom of the page.

There is a '**Speed Bar**' at the top of nearly every page. By clicking the buttons on it you may move from one page of eBER to any other. Example: If you are on the Legal Name/Location Page you may click on the Report button on the Speed Bar, and you will

go directly to the Report page. You could then click the Location button on the Speed Bar to go directly to the Legal Name/Location page.

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### **Saving Information**

Whenever you begin viewing, entering information, or updating information for an establishment, eBER saves your changes in a temporary file. If you have to leave eBER for any reason, you will not lose the information you have entered so far.

When you open an establishment in eBER, eBER gives you a Pre-Confirmation Number (or Pre-Confirm Number). This Pre-Confirmation number appears on the left side of the header of every page in eBER. If you make changes to an establishment's information you can get back to those changes after leaving eBER by providing your Pre-Confirmation Number on the Select Establishment page.

**Important:** To submit changes you make to your establishment's information to us in eBER, you must click the **Submit to FDA for Review** button on the **Report page** of eBER. If you do not click the Submit to FDA for Review button, eBER will save your changes, but not submit them to us.

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## **INDIVIDUAL PAGE DESCRIPTIONS FOR eBER**

### **Select Establishment Page**

On this page you may initiate three activities:

1. You may begin an initial registration of an establishment for which we do not yet have a record.
2. Click on the '**Initial Registration**' button to begin entering information for a new establishment.
3. You may associate one or more existing establishments with you.
4. Click on the '**Edit User Establishments Profile**' button to identify your establishment(s) (so you may view and update your registration and listing information).
5. You may access a record of your establishment in order to view or update it. If you have previously associated an establishment with your account (see #2 above), you may enter your FDA registration number in the appropriate field and click the '**Edit this Establishment**' button to view/update your record. If you have already started making changes to an establishment's information through eBER or have recently submitted changes being reviewed by the FDA, the system will display the Other Submissions Pending page.

There are two types of registration numbers you may use to identify your establishment. You may have one or both types of numbers. If you have both, you need to enter only one to access your data.

Central File Number (CFN): 7-digit number assigned by FDA.

FDA Establishment Identifier number (FEI): 7 to 10-digit number assigned by FDA.

If you have already made changes to an establishment's information through eBER, you can access the establishment's information (including your changes) and continue updating it by supplying the Pre-Confirmation Number eBER assigned you when you initially updated the establishment's information.

### **Buttons**

**Edit this establishment:** See above.

**Initial Registration:** See above.

**Clear:** Clears any text you have entered onto this page.

**Edit User Establishments Profile:** See above.

**View All Active Users:** Takes you to the Active Users page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Registration Profile Page**

On this page you may identify the establishment(s) to which you wish to have access (to view or update) through the eBER system.

In the upper portion of the screen you may enter the registration number of the establishment with which you wish to be associated (either an FEI or a CFN) and the most recent 'Validated by FDA' date for this establishment. The most recent validated date is in the upper right corner of the last Blood Establishment Registration and Product Listing Summary Report we sent you.

Once you have entered a registration number and a 'Validated by FDA' date, click on the '**Add This Establishment**' button to submit your request for access to this establishment. If your registration number and 'Validated by FDA' date are accurate, eBER will grant you access to the establishment immediately. If your registration number and 'Validated by FDA' date do not match our records, eBER will notify you immediately. If you feel that the information you supplied is correct and eBER should have accepted it, use the contact CBER link located at the bottom of the web page to notify us.

Once you have supplied a valid registration number and 'Validated by FDA' date, eBER will associate you with the establishment, and the establishment name will appear in the lower portion of this screen.

The lower portion of the screen lists the establishments you may access. Each establishment listing is prefaced with two buttons '**Edit**' and '**Delete**'.

To view and/or update an establishment click on the '**Edit**' button next to the establishment name. If you have already started making changes to an

establishment's information through eBER or have recently submitted changes for review by the FDA, the system will display the Other Submissions Pending page. To revoke your access to an establishment, click on the '**Delete**' button next to the establishment name. This will NOT delete any information about this establishment. It will simply remove your rights to view or update that establishment's information.

#### **Buttons**

**Add this Establishment:** See above.

**Return to Form Entry:** Returns you to the Select Establishment page.

**Clear Screen:** Clears any text you have entered onto this page.

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#### **Active Users Page**

This page displays a list of all users associated with the same facilities as the current user. For each establishment listed you will see; Establishment Name, FEI, CFN, User Names associated with the establishment, and the First and Last name of those users.

#### **Button**

**Return to Select Establishment page:** Returns you to the Select Establishment page.

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#### **Other Submissions Pending Page**

This page is a notice to you that other electronic submissions are pending for the establishment you are attempting to access. A Pending Submission is:

- An electronic (eBER) record that has been created within the last 30 days but not submitted to the FDA.
- An electronic (eBER) record that has been submitted and is currently awaiting action by the FDA.

To edit a submission listed that has been created but not submitted to the FDA, click the '**Edit**' button next to the record.

To view a submitted record currently awaiting action by the FDA, click the '**View**' button next to the record.

Please note that the list of Other Submissions Pending contains only records that have been created using the eBER system.

#### **Buttons**

**Return To Select Establishment page:** Returns you to the Select Establishment page.

**Create a Blood Establishment Registration and Product Listing:** Creates a new eBER record pre-filled with the most recent FDA received Blood Establishment Registration and Product Listing data for that establishment.

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## Status Page

This page allows you to enter the current status of the Blood Establishment Registration. Only an Active Status will allow you to modify Establishment information. Inactive Status will only allow review and submission of the Blood Establishment and Product Listing. You may not continue with the registration process until a status has been entered.

### Buttons

**Continue:** Takes you to the next page of the application.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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## Legal Name/Location Page

This page allows you to view and/or update your establishment's name and location.

**License Number:** We issue U.S. License Numbers under section 351 of the Public Health Service Act to firms that apply for licensure and otherwise qualify. Licenses are appropriate only for firms engaged in *interstate* commerce. We assign unique license numbers only to Blood Banks, Plasmapheresis Centers, Product Testing Laboratories, and other biologic product manufacturers.

**Parent License Number (Parent Lic No.):** Establishments such as Component Preparation Facilities, Collection Facilities, and Distribution Centers that operate under the license of a parent establishment have the parent U.S. License Number in this field.

**FEI and CFN:** If this is an initial submission for an establishment, the user will be able to enter the FEI or CFN number if known. The system will check if the entered FEI/CFN number already exists and if so, direct the user to select the establishment using the establishment selection screen to modify data for an existing establishment.

**Establishment DUNS:** Starting October 1, 2018, the entry of an Establishment DUNS is required for all Blood Establishment Registrations. The DUNS number is a unique nine-digit identifier for businesses which is generated by Dun & Bradstreet. DUNS number is the required Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act (see 21 CFR 607.25(a)). For more information on DUNS numbers, including methods for obtaining a DUNS, please visit the [Dun & Bradstreet website](#).

**Legal Name and Location:** Provide the legal name (not the "doing-business-as" or other names in Item 5), street address, and telephone number of the actual location. NOTE: If blood collection and laboratory facilities are separated, but register as one establishment because of their close proximity, use the laboratory address.

### Buttons

**Add other names used at this location:** Takes you to the Other Names page where you may provide other names for your facility.

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Other Names Page**

This page allows you to provide any other name by which your facility is commonly known, including any name not shown in the Legal Name Field of the Legal Name/Location Page that is or was used at this location. This includes trade, doing-business-as, and previous names, and names of unaffiliated corporations at the same location. If registered with FDA, include the registration number in parentheses. You must also provide the effective date of the Other Name's first use.

#### **Buttons**

**Add This Name:** Adds the Other Name and the date you entered in the text boxes of this page to your establishment's record.

**Return to Establishment Location Form [does not save]:** Returns you to the Legal Name/Location page. **Note:** eBER will not save any text you entered into the two text boxes.

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### **Reporting Official Page**

This page allows you to view and/or edit the Reporting Official name, institution name if applicable, street address, e-mail address, and telephone number.

#### **Buttons**

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **U.S. Agent Page**

This page allows you to view and/or edit the U.S. agent name, institution name if applicable, street address, e-mail address, and telephone number.

**Note:** U.S. Agent information is required for non-U.S. establishments.

#### **Buttons**

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Owner Type Page**

This page allows you to view and/or update the type of ownership under which your establishment operates.

If your establishment's ownership type is not listed, you may choose '**Not Listed**' from the '**Other**' pull down menu at the bottom of the selections, and type in your ownership type in the text box to the right of the pull down.

#### **Buttons**

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Type of Establishment Page**

This page allows you to view and or update your type(s) of establishment.

Check all applicable boxes that describe your routine operations. If you check Hospital Transfusion Service do not check any other block.

Descriptions of Establishment Types:

**Community (Non-hospital) Blood Bank:** A commercial or non-profit blood collection/processing establishment, not located in a hospital, that may perform product testing and routinely distributes blood and/or blood products to one or more hospitals. We consider an independent blood bank located inside a hospital, but separately operated and owned, to be a Hospital Blood Bank.

**Hospital Blood Bank:** A hospital (or establishment located within a hospital) that routinely collects or processes Whole Blood or blood components. A Hospital Blood Bank may collect components by apheresis or prepare them from Whole Blood. Processing includes freezing, deglycerolizing, washing, irradiating, rejuvenating, or leukocyte-reducing Red Blood Cells. We include hospitals that perform autologous



or directed collections in this category. Hospital Blood Banks usually perform product testing (such as blood grouping and hepatitis testing), as well as compatibility testing. We consider hospitals that solely prepare Red Blood Cells or Recovered Plasma, pool Platelets or Cryoprecipitated AHF for ease of transfusion, or issue bedside leukocyte-reduction filters with blood components to be Hospital Transfusion Services. A hospital that collects Source Plasma under licensure should also check "Plasmapheresis Center."

**Plasmapheresis Center:** An establishment licensed by FDA/CBER that collects Source Plasma or Therapeutic Exchange Plasma for commercial distribution. If you also collect Whole Blood for a licensed establishment, check "Collection Facility" and include the license number of the parent firm. Hospitals that perform plasmapheresis for research purposes only or to prepare transfusion products such as Plasma or Platelets, Pheresis, should NOT check this box.

**Product Testing Laboratory:** A separate establishment that performs routine blood and plasma donor testing. You must also indicate whether you are independent or associated with a Blood Bank.

**Hospital Transfusion Service:** A hospital that performs compatibility testing (cross matching) for blood or blood components but does NOT routinely collect allogeneic or autologous blood, or process Whole Blood into components (except Red Blood Cells and Recovered Plasma). We consider hospitals that freeze, deglycerolize, wash, irradiate, rejuvenate, or reduce the number of leukocytes from Red Blood Cells to be Hospital Blood Banks. You must also indicate your Medicare approval status.

**Component Preparation Facility:** An intermediate processing establishment that prepares components from blood collected by a mobile or fixed collection site but does not perform product testing.

**Collection Facility:** An establishment that performs blood collections or apheresis, but does not test. If you also redistribute the final product after the parent blood bank has processed and returned products to you, then also check Distribution Center.

**Distribution Center:** An establishment that stores blood or blood products FOR TRANSFUSION under specific controlled conditions prior to shipping it to the final user. We do not consider a transfusion service to be a "distribution center" since it holds the product over a relatively short period of time and does not intend to redistribute. If you are a transfusion service operating as a depot or distribution center for a blood bank, register as a Distribution Center and include the license number of the blood bank, if licensed.

**Broker/Warehouse:** A broker, distributor, or warehouse that stores and redistributes source material for further manufacture, such as Recovered Plasma, Source Plasma, and whole blood, red blood cells, or platelets for diagnostic product use.

**Non-Hospital Transfusion Service:** A commercial or non-profit establishment, not located within a hospital, that routinely performs product testing and distribution of blood and blood products to one or more hospitals. Procedures may include compatibility testing (crossmatching), distribution of crossmatched blood products,

red blood cell phenotyping and genotyping, antibody screening and identification, and advanced serologic problem solving.

**Manufacturer of Licensed Devices:** A biologic licensed establishment responsible for production and distribution of medical devices intended for use in the US.

**Other (specify):** This includes independent establishments that irradiate blood products. If your establishment type is not on the list, select 'Other' and enter your establishment type in the adjoining box.

### Buttons

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### Products Page

This page allows you to view and/or update all products that you manufacture for commercial distribution. This includes allogeneic, autologous, and directed collections, or products prepared, tested, or stored for distribution to other firms. See the Product Definition section for information on products.

If one of your manufactured products is not on the list, enter the product on the Other Products page. Navigate to this page by clicking on the '**Add Other Products**' button. Check the list of values for your product. If your product is not on the list, select '**Other**' and enter your product name in the lower box.

Do not list products you do not manufacture, but only hold for final use, such as albumin, reagents, immune globulins, etc. Do not list clinical laboratory services as a product. We do not consider this to be blood product manufacturing. Record compatibility testing in the testing column for the appropriate product.

Do not list any products you collect as a by-product of a therapeutic procedure and immediately destroy. Similarly, exclude products prepared under emergency conditions. We define an emergency as a situation that demands immediate action that a responsible person has suitably documented in writing. Do not list products that you pool or divide into pediatric aliquots.

Indicate Allogeneic, Autologous, or Directed donor types **only if you collect blood products for transfusion (Product lines 1-14, columns 1 or 3)**. Allogeneic donors donate blood intended for transfusion to other than the donor or a known recipient. Autologous donors donate blood intended for transfusion at a later time to the donor. Directed donors donate blood intended for transfusion to a known recipient. If you do not **collect** blood products for transfusion, **do not** check donor types.

### Process Definitions:

**Collect:** refers to collection of whole blood or blood products for transfusion or further manufacturing into injectable or non-injectable products.

**Manual Apheresis:** refers to procedures such as plasmapheresis, plateletpheresis, and leukapheresis, in which you return unneeded portions of the whole blood to the donor.

**Automated Apheresis:** refers to the collection of Red Blood Cells, Platelets, Leukocytes, Granulocytes, or Plasma by automated equipment.

**Prepare:** refers to functions such as component preparation from Whole Blood.

**Leukocytes Reduced:** refers to blood products that you process to remove leukocytes before issue. Leukocyte-reduced products should meet the criteria for residual leukocyte count and product recovery described in FDA recommendations. Do not include products leukocyte reduced during transfusion.

**Irradiated:** refers to irradiation of blood products before transfusion. Check this only if you are performing the irradiation step, or have a contract manufacturing agreement for another establishment to perform the irradiation for you.

**Donor Retested:** refers to storage of products for a minimum of 112 days, until the donor returns for subsequent donation or testing, and all infectious disease markers are negative at the subsequent testing.

**Test:** refers to product testing such as blood grouping, syphilis, hepatitis, HIV, and protein electrophoresis, as well as compatibility testing (cross matching). It does not include daily quality control tests of reagents.

**Store and Distribute to Others:** refers to storage of products under controlled conditions for distribution to other firms.

**Pathogen Reduced:** refers to exposure to a chemical and/or radiation based processing system intended to reduce the risk of transfusion-transmitted infections in blood and blood components.

**Pooled:** individual components, e.g. Cryoprecipitated AHF, Whole Blood-derived platelet concentrates, combined using an aseptic technique. The shelf life is specified in the directions for use for the blood collection, processing, and storage system.

**Bacterial Testing:** is a qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in leukocyte reduced apheresis platelets or pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets within 24 hours prior to transfusion as a safety measure following testing with a growth-based quality control test cleared by the FDA for platelet components.

### **Product Definitions:**

**Whole Blood:** All blood collected from human donors for transfusion to human recipients using an approved anticoagulant preservative solution.

**Red Blood Cells:** Red Blood Cells remaining after separating plasma from human blood, or collected by apheresis.

**RBC Frozen:** Red Blood Cells stored at ultra-low temperature in the presence of a cryoprotective agent, and preserved for potentially long periods of time.

**RBC Deglycerolized:** Red Blood Cells washed free of the glycerol in which they have been stored.

**RBC Reconstituted:** Red Blood Cells to which plasma is added to prepare a Whole Blood product, often with a specific hematocrit, used primarily for pediatric transfusions.

**RBC Washed:** Red Blood Cells typically washed using 0.9% Sodium Chloride, Injection (USP) with or without small amounts of dextrose using manual or automated methods. The washed Red Blood Cells are stored at 1-6° C for up to 24 hours.

**RBC Rejuvenated:** Red Blood Cells treated with a rejuvenating solution, such as pyruvate inosine, to restore cell integrity.

**RBC Rejuvenated Frozen:** Red Blood Cells treated with a rejuvenating solution, then frozen and stored at ultra-low temperatures in the presence of a cryoprotective agent.

**RBC Rejuvenated Deglycerolized:** Red Blood Cells treated with a rejuvenating solution, frozen using a cryoprotective agent, and then washed free of the rejuvenating solution and glycerol.

**Cryoprecipitated AHF:** A preparation containing antihemophilic factor obtained from a single unit of plasma.

**Platelets:** Platelets collected from a single donor and suspended in a specified volume of original plasma.

**Platelets PAS (Platelet Additive Solution):** Isotonic crystalloid nutrient media solution designed to replace a portion of plasma for the storage of apheresis platelet products, allowing the volume of plasma transfused to be decreased.

**Platelets Extended Dating:** Platelets that have been tested for bacteria using an FDA-cleared bacterial detection device labeled as a “safety measure”, following testing with a growth-based quality control test cleared by the FDA for platelet components, that can support extending the expiration date of platelets past 5 days. Platelets shall be stored in a container that is approved or cleared to store platelets up to 7 days.

**Platelets Washed:** Whole Blood derived or apheresis collected platelets washed with 0.9% Sodium Chloride, Injection (USP) or saline-buffered with ACD-A or citrate using manual or automated methods. The washed platelets are stored at 20-24° C for up to 4 hours.

**Granulocytes:** White Blood Cells (leukocytes) collected from a single donor and suspended in a specific volume of original plasma intended for patient infusion.

**Plasma:** The fluid portion of one unit of human blood intended for transfusion which, in a closed system, has been collected, stabilized against clotting, and separated from red cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at -18°C or colder.

**PF24 Plasma:** The fluid portion of one unit of human blood intended for transfusion which has been separated from Whole Blood and placed at -18° C or colder within 24 hours from Whole Blood collection. When prepared by automated apheresis the product is stored at 1° to 6° C within 8 hours of collection and frozen at -18° C or colder within 24 hours of collection.

**PF24RT24 Plasma:** Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) – Prepared

from automated apheresis collections , can be held at room temperature for up to 24 hours after collection and then frozen at -18° C or colder.

**Fresh Frozen Plasma:** Single donor plasma prepared from Whole Blood within 8 hours of collection, or collected by automated apheresis, and stored at -18°C or colder.

**Plasma Cryoprecipitate Reduced:** Plasma from which Cryoprecipitated AHF has been removed.

**Liquid Plasma:** Single donor plasma separated from red cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at 1-6°C.

**Therapeutic Exchange Plasma (TEP):** Plasma obtained from a patient who undergoes plasma exchange (also called therapeutic plasmapheresis). Do not list TEP that you immediately destroy. We consider TEP to be source material for further manufacturing use subject to licensure.

**Source Leukocytes:** White Blood Cells intended as source material for further manufacturing use.

**Source Plasma:** The fluid portion of human blood collected by plasmapheresis (except plasma derived by therapeutic plasma exchange) and intended as a source material for further manufacturing use. This includes source material intended for injectable and non-injectable products.

**Recovered Plasma:** Plasma derived from single units of Whole Blood, Plasma, or as a by-product in the preparation of blood components from Whole Blood, for use in the manufacturing of licensed or unlicensed products.

**Blood Products for Diagnostic Use:** Whole Blood, Red Blood Cells, or Platelets shipped for further manufacture into non-injectable products.

**Blood Bank Reagents:** Diagnostic substances manufactured for commercial distribution used to characterize and determine the acceptability of blood products for transfusion purposes. These include reagent red blood cells, blood grouping reagents and anti-human globulin (AHG).

**Donor Screening IVDs:** In-vitro diagnostic medical devices used in screening blood donors for transfusion-transmitted infections.

**Freeze Dried Plasma:** Dehydrated version of plasma that when reconstituted, is used to replace coagulations factors in bleeding patients.

**Other:** Other products not listed above that you manufacture for commercial distribution.

**Blood Components for Research:** Any blood products which are not for sale, rather are solely for use in clinical or non-clinical studies, teaching, or analysis, including laboratory samples.

**Pooled Plasma SD:** Solvent-detergent (SD) treated, pooled, human plasma.

**Not Listed:** Creates a free-text box for custom product entry.

## Buttons

**Add Other Products:** Takes you to the Additional Products page.

**Continue:** Takes you to the next page of the application.

**Clear:** Clears any text you have entered onto this page.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Additional Products Page**

This page allows you to enter additional products that your establishment manufactures for commercial distribution and indicate what processes you perform for each additional product. Check the list of values for your additional product. If your product is there, select it. If your product is not on the list, select '**Not Listed**' and enter your product name in the lower box.

#### **Buttons**

**Add This Product and Reset Screen:** Adds to your establishment's record the additional product and processes you have entered.

**Clear This Form and Return to Product Form:** Returns you to the Product page.

**Note:** eBER will not save any product and process information displayed in the textbox and checkboxes of this page unless you click on '**Add Product**' first.

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### **Report Page**

This page displays all of the information available for your establishment. This page will display any updates you have made to your establishment's registration and product listing.

You may submit your updates to us by clicking on the '**Submit to FDA for Review**' button. eBER will review all of the information entered for your establishment to ensure that you provided all the required information. If all of the required information is present, eBER will send your request to update your establishment's information to us. eBER will display a notification on the screen that it has submitted your update, and you may print a copy of your submitted information for your records.

**Remove Establishment Dialog:** If a user submits an establishment with a status of "Inactive" then the user will be asked if they wish to remove the establishment from their user profile. The user will select "OK" to remove the establishment or "Cancel" to retain the establishment in their user profile.

#### **Buttons**

**Submit to FDA for Review:** See above. This button does not appear if viewing a submitted report.

**New Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

**Print Form:** Prints a report of your establishment's information (including any updates you have made).

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### **Validation Errors Page**

This page appears when you have attempted to submit an incomplete registration and will display what required data is missing.

Enter data in the fields provided then click the '**Submit Form**' button to save the information you entered.

If no data entry field is provided, return to the data entry form by clicking the appropriate button in the Return to Data Form column.

### **Buttons**

**Submit Form:** Submits your record to the FDA (if all required information has been entered) or Saves your changes and displays any remaining required data that is missing.

**Refresh:** Refreshes your browser window.

**Change Facility:** Returns you to the Select Establishment page.

**CBER On-Line Main Menu:** Returns you to the CBER On-Line Main Menu.

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### **Reporting Problems**

If for any reason you are unable to use the online system, please contact [bloodregis@fda.hhs.gov](mailto:bloodregis@fda.hhs.gov).

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### **Paperwork Reduction Act Statement:**

The Paperwork Reduction Act of 1995 provides that an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0594. The time required to complete this information collection is estimated to average 60 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov) .

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