

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEL: 1570969
CEN: 1570969
2. U.S. LICENSE NUMBER
235

3. REASON FOR SUBMISSION
1. ANNUAL REGISTRATION
2. INITIAL REGISTRATION
3. CHANGE IN INFORMATION



FOR FDA USE ONLY

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in Item 4, and any changes in your mailing address in Item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in Item 8.3 and the phone number of your actual location in Item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (include legal name, number and street, city, state, country, and post office code)

Hoxworth Blood Center University of Cincinnati Medical Center
3130 Highland Avenue, M.L. #0055
P.O. Box 670055
Cincinnati, OH 45267-0055

4.1 PHONE 513-558-1200

5. OTHER NAMES USED AT THIS LOCATION (include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)
Paul L. Hoxworth Blood Center
U. of Cinn. Blood Trans. Serv.

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)

Hoxworth Blood Center University of Cincinnati Medical Center
ATTN: Susan L. Wilkinson, EdD
3130 Highland Ave. ML0055
P.O. Box 670055
Cincinnati, OH 45267-0555

7. U.S. AGENT (include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Susan L. Wilkinson, EdD
8.2 E-MAIL ADDRESS susan.wilkinson@uc.edu
8.3 PHONE 513-558-1271 8.4 DATE

This form is authorized by Sections 510(b), (l) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (g) of the Act (Title 21, United States Code 331(f) and (g)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 333(a)).

9. TYPE OF OWNERSHIP

- 1. SINGLE PROPRIETORSHIP
- 2. PARTNERSHIP
- 3. CORPORATION profit non-profit
- 4. COOPERATIVE ASSOCIATION
- 5. FEDERAL (non-military)
- 6. U.S. MILITARY
- 7. STATE
- 8. COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- 9. OTHER (Specify):

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

- 1. COMMUNITY (NON-HOSPITAL) BLOOD BANK
- 2. HOSPITAL BLOOD BANK
- 3. PLASMAPHERESIS CENTER
- 4. PRODUCT TESTING LABORATORY
- 5. HOSPITAL TRANSFUSION SERVICE
- 6. COMPONENT PREPARATION FACILITY
- 7. COLLECTION FACILITY
- 8. DISTRIBUTION CENTER
- 9. BROKERWAREHOUSE
- 10. OTHER (Specify):

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS	ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT (1)	MANUAL APHERESIS (2)	AUTOMATED APHERESIS (3)	PREPARE (4)	LEUKOCYTES REDUCED (5)	IRRADIATED (6)	DONOR RETESTED (7)	TEST (8)	STORE and DISTRIBUTE to OTHERS (9)
WHOLE BLOOD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>								
RED BLOOD CELLS (RBC)												
RBC FROZEN												
RBC DEGLYCEROLIZED												
RBC REUVENATED												
RBC REUVENATED FROZEN												
RBC REUVENATED DEGLYCEROLIZED												
CRYOPRECIPITATED AHF												
PLATELETS												
LEUKOCYTES/GRANULOCYTES												
PLASMA												
PLASMA CRYOPRECIPITATE REDUCED												
FRESH FROZEN PLASMA												
LIQUID PLASMA												
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUKOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA												
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												