

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

1. REGISTRATION NUMBER

FEI: 1771443

CFN: 1771443

2. U.S. LICENSE NUMBER

3. REASON FOR SUBMISSION

- .1 ANNUAL REGISTRATION
- .2 INITIAL REGISTRATION
- .3 CHANGE IN INFORMATION

FOR FDA USE ONLY

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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.

This form is authorized by Sections 510(b), (j) 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 (p) of the Act (Title 21, United States Code 331(f) and (p)) 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)).

DISTRICT OFFICE: Denver
VALIDATED BY FDA: 06-JUL-2011
PRINTED BY FDA: 18-JUL-2011

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)

Children's Hospital Colorado
Transfusion Medicine Services
B120
13123 E. 16th Avenue
Aurora, CO 80045

4.1 PHONE 720-777-6702

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.)

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

Children's Hospital Colorado
ATTN: Kelley E. Capocelli
13123 E. 16th Avenue
B120
Aurora, CO 80045

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 Kelley E. Capocelli

8.2 E-MAIL ADDRESS Kelley.Capocelli@childrenshospital.org

8.3 PHONE 720-777-6721

8.4 DATE

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
 - a. INDEPENDENT
 - ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- .5 HOSPITAL TRANSFUSION SERVICE
 - a. APPROVED FOR MEDICARE REIMBURSEMENT
 - NOT APPROVED FOR MEDICARE REIMBURSEMENT
- .6 COMPONENT PREPARATION FACILITY
- .7 COLLECTION FACILITY
- .8 DISTRIBUTION CENTER
- .9 BROKER/WAREHOUSE
- .10 OTHER (Specify):

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS

	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	X				X	X		X	
RED BLOOD CELLS (RBC)			X	X	X	X		X	X
RBC FROZEN				X	X			X	
RBC DEGLYCEROLIZED				X	X	X		X	
RBC REJUVENATED									
RBC REJUVENATED FROZEN									
RBC REJUVENATED DEGLYCEROLIZED									
CRYOPRECIPITATED AHF				X		X		X	
PLATELETS			X	X	X	X		X	X
LEUKOCYTES/GRANULOCYTES			X	X		X		X	
PLASMA									
PLASMA CRYOPRECIPITATE REDUCED									
FRESH FROZEN PLASMA			X	X		X		X	X
LIQUID PLASMA									
THERAPEUTIC EXCHANGE PLASMA									
SOURCE LEUKOCYTES									
SOURCE PLASMA									
RECOVERED PLASMA				X				X	X
BLOOD PRODUCTS FOR DIAGNOSTIC USE									
BLOOD BANK REAGENTS									
OTHER									