

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C.

# ESTABLISHMENT LICENSE

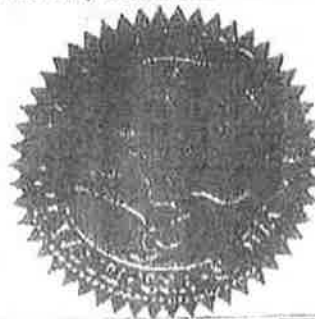
FOR THE MANUFACTURE OF  
BIOLOGICAL PRODUCTS

This is to certify that Establishment License No. 634 is hereby issued  
to Central Kentucky Blood Center, Inc., the manufacturer,  
located at Lexington, Kentucky, through the establishment  
identified as Central Kentucky Blood Center, Inc.  
located at Lexington, Kentucky

DUPLICATE


pursuant to Section 351 of the Public Health Service Act, approved July 1, 1944 (58 Stat. 702, 42 U.S.C. 262), as amended, and the regulations thereunder. The license authorizes the manufacturer to maintain an establishment for the propagation or manufacture and preparation for sale, barter, or exchange in the District of Columbia, or for sending, carrying, or bringing for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsenamine or its derivatives, for which the manufacturer holds an unsuspended and unrevoked product license issued by the Secretary of Health and Human Services pursuant to said Act and regulations.

Date July 7, 1976



*[Signature]*  
Director, Center for Biologics  
Evaluation and Research  
Food and Drug Administration



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING</b>	<b>1. REGISTRATION NUMBER</b> FEI: 3007689681 CFN: <b>2. U.S. LICENSE NUMBER</b> 1836	<b>3. REASON FOR SUBMISSION</b> .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> 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: Cincinnati  
 VALIDATED BY FDA: 30-DEC-2016  
 PRINTED BY FDA: 18-JAN-2017

**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)

Kentucky Blood Center, Inc.  
 3130 Maple Leaf Dr.  
 Lexington, KY 40509

4.1 PHONE 859-327-3223

**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 \_\_\_\_\_

**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.)

Kentucky Blood Center - Andover

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

Kentucky Blood Center, Inc.  
 ATTN: Debra D. Bowman  
 3121 Beaumont Centre Circle  
 Lexington, KY 40513

**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 Debra D. Bowman  
 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org  
 8.3 PHONE 859-519-3717                      8.4 DATE

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	1	<b>X</b>							
RED BLOOD CELLS (RBC)	2		<b>X</b>						
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								
PLATELETS	9		<b>X</b>		<b>X</b>				
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11		<b>X</b>						
PLASMA CRYOPRECIPITATE REDUCED	12								
FRESH FROZEN PLASMA	13								
LIQUID PLASMA	14								
THERAPEUTIC EXCHANGE PLASMA	15								
SOURCE LEUKOCYTES	16								
SOURCE PLASMA	17								
RECOVERED PLASMA	18								
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19								
BLOOD BANK REAGENTS	20								
OTHER	21								

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

1. REGISTRATION NUMBER

FBI: 1048401  
CFN: 1048401

2. U.S. LICENSE NUMBER  
1836

3. REASON FOR SUBMISSION

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

FOR FDA USE ONLY



DISTRICT OFFICE: Cincinnati  
VALIDATED BY FDA: 30-DEC-2016  
PRINTED BY FDA: 18-JAN-2017

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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)

Kentucky Blood Center, Inc.  
10 Stonegate Centre  
Somerset, KY 42503

4.1 PHONE 606-679-7413

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.)

Kentucky Blood Center - Somerset

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

Kentucky Blood Center, Inc.  
ATTN: Debra Bowman, Executive Director of Quality & Reg  
3121 Beaumont Centre Circle  
Lexington, KY 40513-1709

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 Debra Bowman, Executive Director of Quality & Re  
8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org  
8.3 PHONE 859-519-3717 8.4 DATE

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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
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- 7. COLLECTION FACILITY
- 8. DISTRIBUTION CENTER
- 9. BROKER/WAREHOUSE
- 10. OTHER (Specify):


} 1836  
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)
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7.1 E-MAIL ADDRESS 7.2 PHONE		<b>8. REPORTING OFFICIAL'S SIGNATURE</b>  8.1 TYPED NAME Debra Bowman, Executive Director of Quality & Reg 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org 8.3 PHONE 859-519-3717                      8.4 DATE																																																																																																																																																																																																																																																																																																

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING</b>	<b>1. REGISTRATION NUMBER</b> FEI: 3011192341 CFN: <b>2. U.S. LICENSE NUMBER</b> 1836	<b>3. REASON FOR SUBMISSION</b> .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	<b>FOR FDA USE ONLY</b> 
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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 33.3(a)).

DISTRICT OFFICE: Cincinnati  
 VALIDATED BY FDA: 30-DEC-2016  
 PRINTED BY FDA: 18-JAN-2017

**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)

Kentucky Blood Center, Inc.  
 12905 Shelbyville Rd  
 Suite 4  
 Louisville, KY 40243

4.1 PHONE 502-290-0537

**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.)

Kentucky Blood Center - Middletown

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

Kentucky Blood Center  
 ATTN: Debra D. Bowman  
 3121 Beaumont Centre Circle  
 Lexington, KY 40513

**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 Debra D. Bowman

8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org

8.3 PHONE 859-519-3717

8.4 DATE

<b>9. TYPE OF OWNERSHIP</b> .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit___ non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify): _____	<b>10. TYPE ESTABLISHMENT</b> (Check all boxes that describe routine or autologous operations.) .1 <input type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. ___ INDEPENDENT ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. ___ APPROVED FOR MEDICARE REIMBURSEMENT ___ NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input checked="" type="checkbox"/> COLLECTION FACILITY .8 <input type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify): _____
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1836  
 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	1	<input checked="" type="checkbox"/>							
RED BLOOD CELLS (RBC)	2		<input checked="" type="checkbox"/>						
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								
PLATELETS	9		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11		<input checked="" type="checkbox"/>						
PLASMA CRYOPRECIPITATE REDUCED	12								
FRESH FROZEN PLASMA	13								
LIQUID PLASMA	14								
THERAPEUTIC EXCHANGE PLASMA	15								
SOURCE LEUKOCYTES	16								
SOURCE PLASMA	17								
RECOVERED PLASMA	18								
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19								
BLOOD BANK REAGENTS	20								
OTHER	21								

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 0001070402	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:30-DEC-2016 DISTRICT: Cincinnati PRINTED BY FDA:09-JAN-2017																																																																																																																																																																																																																																																																																																																																								
<b>PART I - ESTABLISHMENT INFORMATION</b> 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 0001070402 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____  4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Kentucky Blood Center  3121 Beaumont Centre Circle Lexington, Kentucky 40513-1709  a. PHONE 859-276-2534 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY  5. ENTER CORRECTIONS TO ITEM 4  6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Kentucky Blood Center Attn: Debra Bowman, MT(ASCP)SBB CQA(ASQ) 3121 Beaumont Centre Circle Lexington, Kentucky 40513-1709  a. PHONE 859-519-3717 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____  8. U.S. AGENT  a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Debra Bowman, MT(ASCP)SBB CQA(ASQ) b. E-MAIL dbowman@ckbc.org c. TITLE Exec. Director of Quality & Regulatory d. DATE 29-DEC-2016	<b>PART II - PRODUCT INFORMATION</b> 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="9">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. 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