

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

ESTABLISHMENT LICENSE

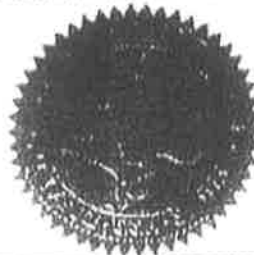
FOR THE MANUFACTURE OF
BIOLOGICAL PRODUCTS

This is to certify that Establishment License No. 634 is hereby issued
to General Kentucky Blood Center, Inc., the manufacturer,
located at Lexington, Kentucky, through the establishment
identified as General 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, 47 U.S.C. 362), as amended, and the regulations thereunder. The License authorizes the manufacturer to maintain an establishment for the propagation or manufacture and preparation for sale, lease, or exchange in the District of Columbia, or for sending, carrying, or holding for sale, lease, 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 similar toxic product, or diagnostic product or its derivatives, for which the manufacturer holds an unexpired and unrevoked product license issued by the Secretary of Health and Human Services pursuant to and in accordance with

Date July 7, 1976



[Signature]
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 1070402 CFN: 1070402 <hr/> 2. U.S. LICENSE NUMBER 1836	3. REASON FOR SUBMISSION 1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION 2 <input type="checkbox"/> INITIAL REGISTRATION 3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY 1 
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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.

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DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 04-DEC-2017
 PRINTED BY FDA: 08-JAN-2018

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.
 3121 Beaumont Centre Circle
 Lexington, KY 40513-1709

4.1 PHONE 859-276-2534

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)

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 & Reg
 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org
 8.3 PHONE 859-519-3717 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 BROKERWAREHOUSE
 10 OTHER (Specify): _____

} U.S. LICENSE NUMBER OF PARENT FIRM _____

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
WHOLE BLOOD	1	X				X			X
RED BLOOD CELLS (RBC)	2		X	X	X	X			X
RBC FROZEN	3			X					X
RBC DEGLYCEROLIZED	4			X		X			X
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								X
RBC REJUVENATED DEGLYCEROLIZED	7			X		X			X
CRYOPRECIPITATED AHF	8			X					X
PLATELETS	9		X		X	X			X
LEUKOCYTES/GRANULOCYTES	10		X			X			X
PLASMA	11								
PLASMA CRYOPRECIPITATE REDUCED	12			X					X
FRESH FROZEN PLASMA	13		X	X		X			X
LIQUID PLASMA	14								
THERAPEUTIC EXCHANGE PLASMA	15								
SOURCE LEUKOCYTES	16								
SOURCE PLASMA	17								
RECOVERED PLASMA	18			X					X
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19								
BLOOD BANK REAGENTS	20								
OTHER Pooled Cryoprecipitate	21			X					X

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 3007689681 CFN: <hr/> 2. U.S. LICENSE NUMBER 1836	3. REASON FOR SUBMISSION 1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION 2 <input type="checkbox"/> INITIAL REGISTRATION 3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY 1  DISTRICT OFFICE: Cincinnati VALIDATED BY FDA: 04-DEC-2017 PRINTED BY FDA: 08-JAN-2018
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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.
 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

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
<input checked="" type="checkbox"/> ALLOGENIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED									
WHOLE BLOOD	1	X							
RED BLOOD CELLS (RBC)	2		X						
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								
PLATELETS	9		X		X				
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11		X						
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								

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 1048401 CFN: 1048401	3. REASON FOR SUBMISSION 1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION 2 <input type="checkbox"/> INITIAL REGISTRATION 3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY 
		2. U.S. LICENSE NUMBER 1836	

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.

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DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 04-DEC-2017
 PRINTED BY FDA: 08-JAN-2018

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

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): _____

1836
 U.S. LICENSE NUMBER OF PARENT FIRM

6. 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 & Reg
 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org
 8.3 PHONE 859-519-3717 8.4 DATE

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(.1)	(.2)	(.3)	(.4)	(.5)	(.6)	(.7)	(.8)	(.9)
WHOLE BLOOD	1	X							
RED BLOOD CELLS (RBC)	2		X						
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								
PLATELETS	9		X		X				
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11		X						
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 FEI: 1000220419 CFN: 1529149	3. REASON FOR SUBMISSION 1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION 2 <input type="checkbox"/> INITIAL REGISTRATION 3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY 
		2. U.S. LICENSE NUMBER 1836	

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DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 04-DEC-2017
 PRINTED BY FDA: 08-JAN-2018

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.
 472 South Mayo Trail
 Pikeville, KY 41501

4.1 PHONE 606-432-4979

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): _____

} 1836
 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 - Pikeville

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
WHOLE BLOOD	1	<input checked="" type="checkbox"/>							<input checked="" type="checkbox"/>
RED BLOOD CELLS (RBC)	2		<input checked="" type="checkbox"/>						<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"/>				<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								

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 & Reg
 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org
 8.3 PHONE 859-519-3717 8.4 DATE

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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.
 12905 Shelbyville Rd
 Suite 4
 Louisville, KY 40243

4.1 PHONE 502-290-0537

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): _____

} 1836
 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 - Middletown

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
	(-1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(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								

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 3013450009 CFN: 2. U.S. LICENSE NUMBER	3. REASON FOR SUBMISSION 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 33.3(a)).

DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 04-DEC-2017
 PRINTED BY FDA: 08-JAN-2018

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.
 2605 Kentucky Ave.
 MP3 Suite 104
 Paducah, KY 42003

4.1 PHONE 270-557-7821

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 BROKERWAREHOUSE
 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 - Paducah

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	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
<input type="checkbox"/> ALLOGENIC <input type="checkbox"/> AUTOLOGOUS <input type="checkbox"/> DIRECTED	(.1)	(.2)	(.3)	(.4)	(.5)	(.6)	(.7)	(.8)	(.9)
WHOLE BLOOD	1								X
RED BLOOD CELLS (RBC)	2								X
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								X
PLATELETS	9								X
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11								
PLASMA CRYOPRECIPITATE REDUCED	12								
FRESH FROZEN PLASMA	13								X
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 ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001070402	2. REASON FOR SUBMISSION 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:04-DEC-2017 DISTRICT: Cincinnati PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
a. BLOOD FDA 2830 NO. FEI: 0001070402 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label				
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	a. Bone											
	b. Cartilage											
	c. Cornea											
	d. Dura Mater											
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia											
	g. Heart Valve											
	h. Ligament											
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium											
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X			X	X	X	X	X			X
l. Sclera												
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
n. Skin												
c. Somatic Cell Therapy <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X				X							X
p. Tendon												
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft												
s. Therapeutic Cells	X	X			X	X	X	X	X			X
t.												
u.												
v.												