

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

# ESTABLISHMENT LICENSE

FOR THE MANUFACTURE OF  
PHARMACEUTICAL PRODUCTS

This is hereby done Establishment License No. 624 is hereby issued  
to General Kentucky Blood Centers, Inc. the manufacturer,  
located at Lexington, Kentucky  
identified as General Kentucky Blood Centers, Inc.  
located at Lexington, Kentucky

QUININE

pursuant to Section 351 of the Food and Drug Service Act, approved July 1, 1944 (58 Stat. 607) and 42 U.S.C. 262, as amended, and the regulations thereunder. The Board authorizes the manufacturer to conduct the manufacturing operations in accordance with the provisions of the Act and the regulations thereunder, and to prepare, package, label, and distribute the product in accordance with the provisions of the Act and the regulations thereunder, provided that the manufacturer shall comply with the provisions of the Act and the regulations thereunder, and shall submit to the Secretary of Health and Human Services, upon request, all information required by the Secretary.

Date: July 7, 1976



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES**

**FEI:** 1070402  
**DUNS:**  
**U.S. License Number:**  
1836

**REASON FOR SUBMISSION**  
Change in Information

**DISTRICT OFFICE:**Cincinnati  
**VALIDATED BY FDA:** 07/30/2018

**LEGAL NAME AND LOCATION:**

Kentucky Blood Center, Inc.  
3121 Beaumont Centre Circle  
Lexington, KY 40513-1709 USA

**REPORTING OFFICIAL:**

Kim Turner, Vice President of Quality and Regulatory Affairs  
Kentucky Blood Center, Inc.  
3121 Beaumont Centre Circle

**U.S. AGENT:**

Lexington, KY 40513-1709 USA  
859-519-3785  
kiturner@kybloodcenter.org

**OTHER NAMES USED IN THIS LOCATION:**

**TYPE OF OWNERSHIP:**  
CORPORATION  
**DONOR/RECIPIENT RELATIONSHIP:**  
ALLOGENIC, AUTOLOGOUS, DIRECTED

**ESTABLISHMENT TYPE:**

COMMUNITY (NON-HOSPITAL) BLOOD BANK

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X					X			X			
RED BLOOD CELLS (RBC)			X	X	X	X			X			
RBC FROZEN				X					X			
RBC DEGLYCEROLIZED				X		X			X			
RBC REJUVENATED FROZEN									X			
RBC REJUVENATED DEGLYCEROLIZED				X		X			X			
CRYOPRECIPITATED AHF				X					X			
PLATELETS			X		X	X			X			
GRANULOCYTES			X			X			X			
FRESH FROZEN PLASMA			X	X		X			X			

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES**

**FEI:** 1070402  
**DUNS:**  
**U.S. License Number:**  
1836

**REASON FOR SUBMISSION**  
Change in Information

**DISTRICT OFFICE:**Cincinnati  
**VALIDATED BY FDA:** 07/30/2018

**LEGAL NAME AND LOCATION:**

Kentucky Blood Center, Inc.  
3121 Beaumont Centre Circle  
Lexington, KY 40513-1709 USA

**REPORTING OFFICIAL:**

Kim Turner, Vice President of Quality and Regulatory Affairs  
Kentucky Blood Center, Inc.  
3121 Beaumont Centre Circle

**U.S. AGENT:**

Lexington, KY 40513-1709 USA

859-519-3785

kiturner@kybloodcenter.org

859-276-2534

**OTHER NAMES USED IN THIS LOCATION:**

**TYPE OF OWNERSHIP:**  
CORPORATION  
**DONOR/RECIPIENT RELATIONSHIP:**  
ALLOGENIC, AUTOLOGOUS, DIRECTED

**ESTABLISHMENT TYPE:**

COMMUNITY (NON-HOSPITAL) BLOOD BANK

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
PLASMA CRYOPRECIPITATED REDUCED				X					X			
RECOVERED PLASMA				X					X			
POOLED CRYOPRECIPITATE				X					X			

\*\*\*\*\* End Of Report \*\*\*\*\*

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES**

**FEI:** 3007689681  
**DUNS:**  
**U.S. License Number:**  
1836

**REASON FOR SUBMISSION**  
Change in Information

**DISTRICT OFFICE:**Cincinnati  
**VALIDATED BY FDA:** 07/30/2018

**LEGAL NAME AND LOCATION:**

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

**REPORTING OFFICIAL:**

Kim Turner, Vice President of Quality and Regulatory Affairs  
Kentucky Blood Center, Inc.  
3121 Beaumont Centre Circle

**U.S. AGENT:**

859-327-3223

Lexington, KY 40513 USA  
859-519-3785  
kiturner@kybloodcenter.org

**OTHER NAMES USED IN THIS LOCATION:**

Central Kentucky Blood Center - Andover, Kentucky Blood Center -  
Andover, Kentucky Blood Center Inc.

**TYPE OF OWNERSHIP:**

CORPORATION

**DONOR/RECIPIENT RELATIONSHIP:**

ALLOGENIC, AUTOLOGOUS, DIRECTED

**ESTABLISHMENT TYPE:**

COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

\*\*\*\*\* End Of Report \*\*\*\*\*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
 BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
 MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES

FEI: 3011192341  
 DUNS:  
 U.S. License Number:  
 1836

REASON FOR SUBMISSION  
 Change in Information

DISTRICT OFFICE: Cincinnati  
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.  
 12905 Shelbyville Rd  
 Suite 4  
 Louisville, KY 40243 USA  
 502-290-0537

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs  
 Kentucky Blood Center  
 3121 Beaumont Centre Circle  
 Lexington, KY 40513 USA  
 859-519-3785  
 kiturner@kybloodcenter.org

U.S. AGENT:

OTHER NAMES USED IN THIS LOCATION:  
 Kentucky Blood Center - Middletown; Kentucky Blood Center, Inc

TYPE OF OWNERSHIP:  
 CORPORATION

DONOR/RECIPIENT RELATIONSHIP:  
 ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:  
 COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL	AUTOMATED	PREPARE	LEUKOCYTES	IRRADIATED	DONOR	TEST	STORE AND	BACTERIAL	PATHOGEN	POOLED
		APHERESIS	APHERESIS		REDUCED		RETESTED		DISTRIBUTE TO OTHERS	TESTING	REDUCED	
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

\*\*\*\*\* End Of Report \*\*\*\*\*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
 BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
 MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES

FEI: 3013450009  
 DUNS:  
 U.S. License Number:

REASON FOR SUBMISSION  
 Change in Information

DISTRICT OFFICE: Cincinnati  
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.  
 2605 Kentucky Ave.  
 MP3 Suite 104  
 Paducah, KY 42003 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs  
 Kentucky Blood Center, Inc.  
 3121 Beaumont Centre Circle

U.S. AGENT:

270-557-7821

Lexington, KY 40513 USA  
 859-519-3785  
 kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Kentucky Blood Center - Paducah

TYPE OF OWNERSHIP:

CORPORATION

ESTABLISHMENT TYPE:

DISTRIBUTION CENTER

DONOR/RECIPIENT RELATIONSHIP:

PRODUCT	COLLECT	MANUAL	AUTOMATED	PREPARE	LEUKOCYTES	IRRADIATED	DONOR	TEST	STORE AND	BACTERIAL	PATHOGEN	POOLED
		APHERESIS	APHERESIS		REDUCED				DISTRIBUTE TO OTHERS			
WHOLE BLOOD									X			
RED BLOOD CELLS (RBC)									X			
CRYOPRECIPITATED AHF									X			
PLATELETS									X			
FRESH FROZEN PLASMA									X			

\*\*\*\*\* End Of Report \*\*\*\*\*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
 BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
 MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES

FEI: 1000220419  
 DUNS:  
 U.S. License Number:  
 1836

REASON FOR SUBMISSION  
 Change in Information

DISTRICT OFFICE: Cincinnati  
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.  
 472 South Mayo Trail  
 Pikeville, KY 41501 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs  
 Kentucky Blood Center, Inc.  
 3121 Beaumont Centre Circle

U.S. AGENT:

Lexington, KY 40513-1709 USA

859-519-3785

kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Central Kentucky Blood Center, Inc.; Kentucky Blood Center -  
 Pikeville; Kentucky Blood Center Inc.

TYPE OF OWNERSHIP:

CORPORATION

DONOR/RECIPIENT RELATIONSHIP:

ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:

COLLECTION FACILITY; DISTRIBUTION CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X								X			
RED BLOOD CELLS (RBC)			X						X			
PLATELETS			X		X				X			
PLASMA			X									

\*\*\*\*\* End Of Report \*\*\*\*\*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
 BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
 MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES

FEI: 1048401  
 DUNS:  
 U.S. License Number:  
 1836

REASON FOR SUBMISSION  
 Change in Information

DISTRICT OFFICE: Cincinnati  
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

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

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs  
 Kentucky Blood Center, Inc.  
 3121 Beaumont Centre Circle

U.S. AGENT:

606-679-7413

Lexington, KY 40513-1709 USA  
 859-519-3785  
 kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Central Kentucky Blood Center, Inc.; Kentucky Blood Center -  
 Somerset; Kentucky Blood Center Inc.

TYPE OF OWNERSHIP:

CORPORATION

ESTABLISHMENT TYPE:

COLLECTION FACILITY

DONOR/RECIPIENT RELATIONSHIP:

ALLOGENIC, AUTOLOGOUS, DIRECTED

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

\*\*\*\*\* End Of Report \*\*\*\*\*



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR  
MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES**

**FEI:** 3014276808  
**DUNS:**  
**U.S. License Number:**  
1836

**REASON FOR SUBMISSION**  
Change in Information

**DISTRICT OFFICE:**Cincinnati  
**VALIDATED BY FDA:** 07/30/2018

**LEGAL NAME AND LOCATION:**

Kentucky Blood Center, Inc.  
Kentucky Blood Center, Inc  
5406 Antle Drive  
Suite 101  
Louisville, KY 40229 USA  
502-915-0989

**REPORTING OFFICIAL:**

Kim Turner, Vice President of Quality and Regulatory Affairs  
Kentucky Blood Center  
3121 Beaumont Centre Circle  
Lexington, KY 40513 USA  
859-519-3785  
kiturner@kybloodcenter.org

**U.S. AGENT:**

**OTHER NAMES USED IN THIS LOCATION:**

Kentucky Blood Center - Hillview

**TYPE OF OWNERSHIP:**  
CORPORATION  
**DONOR/RECIPIENT RELATIONSHIP:**  
ALLOGENIC, AUTOLOGOUS, DIRECTED

**ESTABLISHMENT TYPE:**  
COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											

\*\*\*\*\* End Of Report \*\*\*\*\*

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.  INITIAL REGISTRATION / LISTING  
 b.  ANNUAL REGISTRATION / LISTING  
 c.  CHANGE IN INFORMATION  
 d.  INACTIVE

See Instructions for OMB Statement. FORM APPROVED OMB No. 0910-0543. Expiration Date: 6/30/2020  
 VALIDATION FOR FDA USE ONLY  
 VALIDATED BY FDA: 04DEC-2017  
 DISTRICT: Cincinnati  
 PRINTED BY FDA: 27-JAN-2018

**PART I - ESTABLISHMENT INFORMATION**

**3. OTHER FDA REGISTRATIONS**  
 a. BLOOD FDA 2830 NO. FEI: 0001070402  
 b. DEVICES FDA 2891 NO. \_\_\_\_\_  
 c. DRUG FDA 2856 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.  SATELLITE RECOVERY ESTABLISHMENT  
 (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)  
 c.  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, MTT(ASCP)SBB COA(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, MTT(ASCP)SBB COA(ASQ)  
 b. E-MAIL dbowman@kybloodcenter.org  
 c. TITLE Vice President, Quality & Regulatory  
 d. DATE 04-DEC-2017

FORM FDA - 3356 (7/17)

**PART II - PRODUCT INFORMATION**

**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS**

Types of HCT / Ps	Establishment Functions					Label	Distribute	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)
	Recover	Screen	Test	Package	Process						
a. Bone											
b. Cartilage											
c. Cornea											
d. Dura Mater											
e. Embryo											
f. Fascia											
g. Heart Valve											
h. Ligament											
i. Oocyte											
j. Pericardium											
k. Peripheral Blood Stem											
l. Sclera											
m. Semen											
n. Skin											
o. Somatic Cell Therapy Products											
p. Tendon											
q. Umbilical Cord Blood											
r. Vascular Graft											
s. Therapeutic Cells											
t. _____											
u. _____											
v. _____											

**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)**

**15. TYPE OF HCT/PS**

**16. TYPE OF HCT/PS**

**17. TYPE OF HCT/PS**

**18. TYPE OF HCT/PS**

**19. TYPE OF HCT/PS**

**20. TYPE OF HCT/PS**

**21. TYPE OF HCT/PS**

**22. TYPE OF HCT/PS**