

BLOOD ESTABLISHMENT

Name	Life stream	Blood	Bunk
Amount			

6/7/24-01-8601-80015

lf 0597628200 02583





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Revenue: 0597	7628200			
	Blood Establis	hment Re	egistration A	Application
Select one:	New Registration □ Change in Standing		Change of Owners Renewal of Regis	
Check 0	ne			
☐ Limited L		Limited Par Municipality Municipality Municipality Non-Profit	y (City) y (County) Corporation	 ☐ Sole Proprietor ☐ State Government Agency ☐ Tribal Government Agency ☐ Trust
1. Demo	ographic Informati	on		
Legal Owner	553 015 NOperator Name STREAM Block	D BANK	Federal Tax ID (FE	• ***
	WEST ORANGE	SHOW 7	ROAD	
City	BERNARDINO	State	Zip Code 92408	SAN BERNARDING
Phone (enter	r 10 digit #)	. 386.68	Fax (enter 10 di	
REGUL Facility/Agen		AM. ORG	Web Address	JIFESTREAM CASCADE, OR
LIFES- Physical Add	TREAM BLOOD THESS	BANK		
City	336 STREE	State	Zip Code	County
FEDERA	AL WAY	WA	98003	KING COUNTY
	ne (enter 10 digit #)		Fax (enter 10 d	
Mailing Addr	ess (If different than physical	address)	ТВР	
City	ME AS ABOVE)	State	Zip Code	County

2. Client Information	
List all of your clients in Washington State. Include curre pages as needed.	ent and valid email addresses for each. Attach additional
Client Name	Client Email Address
NONE AT THIS TIME.	
-4	
X .	
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3. Contact Information								
CHHAVY THANG			Title DIRECTOR, REGULATION					
Phone (enter 10 digit #)		Email Add	Proces					
The tion of the cight in y		Lindii Address						
909.386.6822		THANK	CHE LSTREAM. DRG					
Contact Person Name	e fact of M		Title					
Rosen Barra			Title VICE PRESIDENT,					
Phone (enter 10 digit #)		Email Add	WUALITY ! KEGULATORY					
		Linali Add	11633					
98.386.6821		BAYE	RROR LSTREAM ORG					
4. Change of Ownersh	ip Information	on	11 三型 医静脉 11 (三型金)注题的					
Previous Name of Facility	Previous L	icense #	Effective Date of Ownership Change					
	Sig	nature						
I certify I have received, read, unde category. I also certify the information	rstood, and agree to on herein submitted	comply with s is true to the b	state law and rule regulating this licensing pest of my knowledge and belief. May 30, 2024					
Signature of Owner/Authorized Rep	resentative		Date					
ROBERT SANCHE	Z		PRESIDENT / CEO Print Title					
Print Name			Print Title					

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RCW/WAC and Online Website Links

RCW/WAC Links

Administrative procedures and requirements, WAC 246-12

Blood Establishments Laws, RCW 70.335

Blood Establishments Rules, WAC 246-339

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

ESTABLISHMENT LICENSE

FOR THE MANUFACTURE OF BIOLOGICAL PRODUCTS

to	rtify that Establishment License No. 226 Blood Bank of San Bernardino and Riverside Counties	, the manufacturer,
located at	San Bernardino, California	through the establishment
identified as	Blood Bank of San Bernardino and Riverside Counties	· · · · · · · · · · · · · · · · · · ·
pursuant to Sec	San Bernardino, California ction 351 of the Public Health Service Act, approved July 1, 1944 (58 Sthe regulations thereunder. The license authorizes the manufacturer to	stat. 702, 42 U.S.C. 262), as

Date DEC 04 1981



Director, Bureau of Biologics Food and Drug Administration JUN 07 2024

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: 2074143 DUNS: 030592323 U.S. License Number: 226	REASON FOR SUBMISSION Annual Registration	DISTRICT OFFICE:Los Angeles VALIDATED BY FDA: 11/28/2023				
LEGAL NAME AND LOCATION:	REPORTING OFFICIAL: Chhavy Thang	-	U.S. AGENT:				
Blood Bank of San Bernardino and Riverside Counties 384 West Orange Show Road San Bernardino, CA 92408 USA	LifeStream 384 W. Orange Show Road						
	San Bernardino, CA 92408 USA	4					
909-885-6503	909-386-6822 Regulatory@LStream.org						
OTHER NAMES USED IN THIS LOCATION: (DBA) LifeStream - San Bernardino	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: COMMUNITY (NON-HOSPITAL) BLOOD BANK				
	DONOR/RECIPIENT RELATION ALLOGENIC, AUTOLOGOUS		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	4.3	12.5	x	0.3917	12.00 May 1	
RED BLOOD CELLS (RBC)			х	X	х	х		X	x			
RBC FROZEN				X	X		1	X	x			
RBC DEGLYCEROLIZED			- *	X	x	х		x	X			
CRYOPRECIPITATED AHF			-35 /5-	X			3.0		х			х
PLATELETS			х		х	х		X.	х		x	
PLATELETS EXTENDED DATING			X	i ikupana	x	х		X	х	x		
GRANULOCYTES			x	X		X	r Lair	X	x			
PF24 PLASMA		2 2 2 2 2 2	X	X					x			
PF24RT24 PLASMA			x	X					x			

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LEGAL NAME AND LOCATION: Blood Bank of San Bernardino and Riverside Counties 384 West Orange Show Road San Bernardino, CA 92408 USA	REPORTING OFFICIAL: Chhavy Thang LifeStream 384 W. Orange Show Road		U.S. AGENT:			
909-885-6503	San Bernardino, CA 92408 USA 909-386-6822 Regulatory@LStream.org					
OTHER NAMES USED IN THIS LOCATION: (DBA) LifeStream - San Bernardino	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: COMMUNITY (NON-HOSPITAL) BLOOD BANK			
	DONOR/RECIPIENT RELATIO ALLOGENIC, AUTOLOGOUS,		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
FRESH FROZEN PLASMA			x	X					x	1/12	The second	- Transis
PLASMA CRYOPRECIPITATED REDUCED				Х					х			PRA
LIQUID PLASMA				Х	- S	х			х	111		177.
RECOVERED PLASMA				Х					х			1.
BLOOD PRODUCTS FOR DIAGNOSTIC USE				х					x			
RECONSTITUTED WHOLE BLOOD				X		Х		X				

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

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CREDENTIALING



Dear Licensee:

Attached below is your license for the production of Biologics. Your license is void after the expiration date below.

NOTE: Application for renewal of license must be filed with the department not less than 10 days prior to its expiration date and shall be accompanied by the annual renewal fee. Failure to make a timely renewal shall result in expiration of the license.

LIFESTREAM - SAN BERNARDINO PO BOX 1429 SAN BERNARDINO, CA 92408

OFFSITE COLLECTION:

SAN BERNARDINO DONOR CENTER ----- SAN BERNARDINO, CA RIVERSIDE DONOR CENTER ----- RIVERSIDE, CA ONTARIO DONOR CENTER -- ONTARIO, CA MURRIETA DONOR CENTER-- MURRIETA, CA LA QUINTA DONOR CENTER -----LA QUINTA, CA HIGH DESERT DONOR CTR - VICTORVILLE - VICTORVILLE, CA

California Health and Safety Code, Section 1615. Automatic revocation; new license prior to change; proceedings for denial.

(a) A license shall be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. However, a new license may be secured for the new location, owner or person in charge prior to the actual change, provided the contemplated change is in compliance with all the provisions of this chapter, and regulations pertaining thereto.

(b) Proceedings for denial of license shall be conducted in accordance with Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code.

QUESTIONS AND INFORMATION: If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH Laboratory Field Services, Biologics 850 Marina Bay Parkway, Bldg. P-1st Floor Richmond, CA 94804

Email: LFSBiologics@cdph.ca.gov

PublicHealth

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

ICENSE FOR THE PRODUCTION OF BIOLOGICS

LIFESTREAM - SAN BERNARDINO

384 ORANGE SHOW ROAD SAN BERNARDINO, CA 92408

OWNER(S):

BLOOD BANK OF SAN BERNARDINO AND **RIVERSIDE COUNTIES**

9021

BLOOD BANK ID NUMBER

July 23, 2024 EXPIRATION DATE

> July 24, 2023 ISSUANCE DATE

PRODUCTS

CRYOPRECIPITATED AHE CRYOPRECIPITATED AHF - POOLED PLATELETS - PRT PLATELETS EXTENDED DATING **GRANULOCYTES PHERESIS** IRRADIATED PLATELETS, PHERESIS - LR IRRADIATED RBCs LR

> FFP FP-24

LIQUID PLASMA NEONATAL ALIQUOTS PLASMA - THAWED (5-DAY) PLASMA FOR MANUFACTURE PLATELETS PHERESIS - LR **RBC RECONSTITUTED** RBCs - DEGLYCEROLIZED

RBCs - PHERESIS - LR RBCs - WASHED THERAPEUTIC PHLEBOTOMY WHOLE BLOOD RBCs - LR **COVID-19 CONVALESCENT PLASMA** OFF-SITE DISTRIBUTION

MEDICAL DIRECTOR(S):

TUAN LE, MD

FREDERICK B. AXELROD, MD

Branch Chief, Laboratory Field Services





JUN 07 2024

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Application Instructions Checklist

When your application for a blood establishment registration is received by the Department of Health, you will be notified of any outstanding documentation needed to complete the application process.

Indicate type of application:

- New—First time requesting a blood establishment registration.
- Change in Ownership—When name of legal owner/operator changes resulting from the sale of blood establishment.
- Change in Standing—When the blood establishment has a change in standing of its FDA license.
- Renewal—Annual renewal of your blood establishment registration.

1	Check One:
	Please check your legal owner/operator business structure type according to your Washington State Master Business License.
Ø	Application Fees: Fees are non-refundable. You can check the online <u>fee page</u> for current fees.
	1. Demographic Information:

Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #'s. City, county, and state government departments also have UBI#'s.

Federal ID Number (FEIN #): Enter your Federal ID Number, if the business has been issued one.

Legal Owner/Operator Name: Enter the owner's name as it appears on the UBI/ Master Business License.

Mailing Address: Enter the owner's complete mailing address.

Phone and Fax Numbers: Enter the owner's phone and fax number.

Email and Web Address: Enter the owner's email and agency Web addresses, if they have them.

Facility/Agency Name: Enter the agency's name or doing business as (dba) name as advertised on signs, brochures or websites, if different from legal owner/operator name.

Physical Address: Enter the agency's physical street location including city, state, zip code, and county.

Email address: Enter the agency's email address if available.

Phone and Fax Numbers: Enter the agency's phone and fax number.

Mailing Address: Enter the agency's mailing address, if different than physical address.

4	2. Client Information: List all of your clients in Washington State. Include current and valid email addresses for each. Attach additional pages as needed.
Ø	3. Contact Information: Enter name, title, phone number, fax number, and email address.
Ø	4. Change of Ownership Information (if applicable): List the previous legal owner name, previous name of facility, previous license number, and effective date of ownership change.
Z	Signature:
	Signature of legal owner or authorized representative.
	Date signed.
	Print name of legal owner or authorized representative.
	Print title of legal owner or authorized representative

Additional Requirements:

In addition to the application and registration fees, you must submit the following:

Provide proof of the blood establishments current FDA licensure.



Copies of any disciplinary actions issued upon or active against the blood establishments FDA license within the last two years. This may include:

- Titled letters, fines, license suspensions, or revocations issued by the FDA.
 and/or
- · Judicial consent decrees.

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7020 0640 0002 2897 8759



384 W. Orange Show Rd., San Bernardino, CA 92408

WASHINGTON STATE DEPARTMENT OF HEALTH P.O. BOX 1099 OLYMPIA WA 98507-1099



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FIRST-CLASS MAIL

05/31/2024 US POSTAGE \$006.03^o



ZIP 92408 041M11452315



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Blood Establishment Registration - Report

Submitted To FDA

Confirmation Number: 76329

Submitted by: LifeStream Regulatory on 08/15/2024

This report has been submitted to the FDA. Report is now in view only mode.

To make changes to this registration, wait until we have accepted this report, then select this establishment and submit a new report with the new changes.

LEGAL NAME AND LOCATION

Central File Number (CFN):

FDA Establishment Identifier (FEI):

Applicant License Number:

Parent License Number: 226

Establishment DUNS: 119297041

Current Status: PRE-REGISTERED

Applicant Name:

Legal Name: LifeStream Blood Bank

Address: 909 S 336th St Ste B102

City: Federal Way

State: Washington

Zip: 98003

Country: UNITED STATES

Phone: 877-242-5663

District Office: Seattle

OTHER NAMES USED AT THIS LOCATION

New Other Name(s): LifeStream Cascade Region

MAILING ADDRESS OF REPORTING OFFICIAL

Organization: LifeStream Blood Bank

Reporting Official Name: Chhavy Thang

Address: 384 Orange Show Road

City: San Bernardino

State: California

Zip: 92408

Country: UNITED STATES

Phone: 909-386-6822

Foreign Phone:

Email: Regulatory@LStream.org

TYPE OF OWNERSHIP

Corporation: Non-Profit

ESTABLISHMENT TYPE

Collection Facility

	9-					1					-1	
Allogeneic		MANUAI	AUTOMATED		LEUKOCYTES		DONOR		STORE AND DISTRIBUTE	BACTERIAL	PATHOGEN	
✓ Autologous	COLLECT (1)	APHERESIS	AUTOMATED APHERESIS	PREPARE (4)	REDUCED	IRRADIATED (6)	RETESTED	TEST (8)	DISTRIBUTE TO OTHERS	TESTING	REDUCED	POOLED (12)
☑ Directed	('')	(2)	(3)	('')	(5)	(0)	(7)	(0)	(9)	(10)	(11)	(12)
(1) WHOLE BLOOD	6											
(2) RED BLOOD CELLS												
(RBC)			~		~							
(3) RBC FROZEN												
(4) RBC												
DEGLYCEROLIZED												
(5) RBC												
RECONSTITUTED												
(6) RBC WASHED												
(7) RBC REJUVENATED												
(8) RBC REJUVENATED FROZEN												
(9) RBC REJUVENATED												
DEGLYCEROLIZED												
(10) CRYOPRECIPITATED												
AHF												
(11) PLATELETS			~		~							
(12) PLATELETS PAS												
(PLATELETS ADDITIVE												
SOLUTION)												
(13) PLATELETS												
EXTENDED DATING												
(14) PLATELETS WASHED												
(15) GRANULOCYTES												
(16) PLASMA												
(17) PF24 PLASMA			~									
(18) PF24RT24 PLASMA			~									
. ,												
(19) FRESH FROZEN PLASMA			~									
(20) PLASMA	-											
CRYOPRECIPITATED												
REDUCED												
(21) LIQUID PLASMA												
(22) THERAPEUTIC												
EXCHANGE PLASMA												
(23) SOURCE												
LEUKOCYTES												
(24) SOURCE PLASMA												
(25) RECOVERED												
PLASMA												
(26) BLOOD PRODUCTS FOR DIAGNOSTIC USE												
(27) BLOOD BANK												
REAGENTS												
(28) DONOR SCREENING												
IVDs												
(29) FREEZE DRIED												
PLÁSMA	l											

New Facility | CBER On-Line | Print Form

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FDA / Center for Biologics Evaluation and Research

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: 3032023803 DUNS: 119297041 U.S. License Number: 226	REASON FOR SUBMISSION	DISTRICT OFFICE: Seattle VALIDATED BY FDA: 08/27/2024			
LEGAL NAME AND LOCATION: Blood Bank of San Bernardino and Riverside Counties 909 S 336th St Ste B102 Federal Way, WA 98003 USA	REPORTING OFFICIAL: Chhavy Thang LifeStream Blood Bank 384 Orange Show Road		U.S. AGENT:			
877-242-5663	San Bernardino, CA 92408 USA 909-386-6822 Regulatory@LStream.org					
OTHER NAMES USED IN THIS LOCATION: LifeStream Cascade Region	TYPE OF OWNERSHIP: CORPORATION		ESTABLISHMENT TYPE: COLLECTION FACILITY			
	DONOR/RECIPIENT RELATIO ALLOGENIC, AUTOLOGOUS,					

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	Х									·		
RED BLOOD CELLS (RBC)			Х		Х							
PLATELETS			Х		Х							
PF24 PLASMA			Х									
PF24RT24 PLASMA			Х									
FRESH FROZEN PLASMA			Х									

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