

# APPLICATION FOR RENEWAL OF LICENSE FOR THE PRODUCTION OF BIOLOGICS

Division 2, Chapter 4, California Health and Safety Code

## Our records show that the License for the Production of Biologics:

ID number	•	_____
Name	•	_____
Address	•	_____
City, State, ZIP code	•	_____

Expires on: • \_\_\_\_\_

### INSTRUCTIONS: Read all of the items below before completing and mailing your renewal.

Visit our website for more information: <https://go.usa.gov/xPkSy> (cAsE sensitive)

- Complete forms LAB 175 (Biologics License Renewal) and LAB 118 (Personnel Report) for each of your sites. Download the forms here: <https://go.usa.gov/xPkJE> (cAsE sensitive)
- Enclose check/money order - Payable to "California Department of Public Health"
- Mail the necessary forms, documents, and annual renewal fee to:  
California Department of Public Health  
Laboratory Field Services (Biologics)  
850 Marina Bay Parkway, Building P, 1<sup>st</sup> Floor,  
Richmond, CA 94804

*Note: Application for a renewal must be submitted to the Department with fee not less than 10 days prior to the expiration date indicated. Failure to make a timely renewal shall result in expiration of the license. (Section 1616, California Health and Safety Code)*

#### Reminders:

- Changes in ownership, person in charge of biologics production, medical director, or location of facility require a new application. Visit our website for instructions on how to submit an "Initial Application."
- Update changes on page 2 to correct the number and location of collection centers operating under this license, if necessary.
- Update changes on page 2 if biologics collected, processed, stored, or distributed are not correct on your current license.
- Submit the approximate number of each type of Biologic product produced during the past year on page 2. Note: Production includes collection, processing, storage, or distribution.

APPLICATION IS HEREBY MADE FOR RENEWAL OF THE LICENSE FOR PRODUCTION OF BIOLOGICS.

Signature of person in charge of biologics production or medical director:

Title:

Printed name:

Signed this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_ in \_\_\_\_\_, California.

Day

Month

Year

City

2. Our records indicate your facility operates the following off-site collection centers. If the information is **incorrect**, include updated information with your renewal.


3. List any non-acute care California facilities to which you supply blood or blood components. You may use additional pages if necessary.

4. The biologics collected, processed, stored, or distributed are not correctly shown on the current license; please make these changes.

ADD	DELETE

5. Submit the approximate number of each type of biologic product produced during the past year.

Approx. #	Biologic Product
	CRYOPRECIPITATED AHF
	CRYOPRECIPITATED AHF – POOLED
	FFP
	FP-24
	GRANULOCYTES PHERESIS
	HPC – A
	HPC – C – PRIVATE
	HPC – C – PUBLIC
	IRRADIATED BLOOD COMPONENTS
	IRRADIATED PLATELETS, PHERESIS – LR
	IRRADIATED RBCs LR
	LIQUID PLASMA
	NEONATAL ALIQUOTS
	OFF-SITE DISTRIBUTION
	PLASMA – THAWED (5-DAY)
	PLASMA FOR MANUFACTURE
	PLASMA FROZEN WITHIN 24 HRS AFTER PHLEBOTOMY
	PLATELETS – LR
	PLATELETS – PRT
	PLATELETS EXTENDED DATING
	CAR T CELLS

Approx. #	Biologic Product
	PLATELETS PAS (PLATELETS ADDITIVE SOLUTION)
	PLATELETS PHERESIS
	PLATELETS PHERESIS – LR
	PLATELETS PHERESIS, PLASMA REDUCED
	RBC RECONSTITUTED
	RBCs
	RBCs – DEGLYCEROLIZED
	RBCs – FROZEN
	RBCs – PHERESIS – LR
	RBCs – REJUVENATED
	RBCs – WASHED
	SOURCE LEUKOCYTES
	SOURCE PLASMA
	THERAPEUTIC PLASMA EXCHANGE
	THERAPEUTIC PHERESIS
	THERAPEUTIC PHLEBOTOMY
	WHOLE BLOOD
<b>OTHER:</b>	

# FOR CORD BLOOD BANKS OR CORD PRODUCTS ONLY

**1. NAME OF ACCREDITING AGENCY:**

AABB                       NONE  
 FACT                         OTHER:

**2. ARE CORD BLOOD UNITS PROCESSED IN-HOUSE?**

YES

NO – if NO, provide the following information:

- NAME OF FACILITY:
- NAME OF ACCREDITING AGENCY:     AABB         FACT         OTHER:
- BIOLOGICS ID NUMBER:
- FDA LICENSE OR REGISTRATION NUMBER:

**3. DOES YOUR FACILITY COLLECT, PROCESS, STORE, OR DISTRIBUTE CORD BLOOD OR CORD BLOOD PRODUCTS FOR NON-HEMATOPOETIC OR NON-IMMUNOLOGIC RECONSTITUTION?**

NO

YES – if YES, provide the following information:

- SOURCE/SUPPLIER OF RAW PRODUCT:
- DOES YOUR FACILITY HAVE A VERIFIABLE IND?     YES     NO
  - IND NUMBER:
  - IRB CONTACT INFORMATION: 
    - NAME
    - PHONE
    - ADDRESS
- NAME AND CONTACT INFORMATION FOR FACILITY THAT PERFORMS INFECTIOUS DISEASE TESTING (IDT) AND/OR STERILITY TESTING
  - IDT
    - NAME
    - PHONE
    - ADDRESS
  - STERILITY
    - NAME
    - PHONE
    - ADDRESS



## FACILITIES LICENSED FOR THE PRODUCTION OF BLOOD AND BLOOD COMPONENTS (BIOLOGICS)

### Subject: FEE SCHEDULE

The fee schedule for both initial application and renewal of Biologics Licenses is determined by Section 1616.5 of the California Health and Safety Code (CHSC), and adjusted by the annual fee provisions of CHSC 100450, subdivision (a).

<https://go.usa.gov/xPMxP>

*(cAsE sensitive)*

**PLEASE BE ADVISED THAT THERE IS NO LONGER AN EXEMPTION  
FROM PAYMENT OF FEES BY ANY FACILITY.**

CHSC 1616. Fees: expiration; renewal.

- (a) Each application for license or license renewal under this chapter shall be accompanied by a fee determined by the director of regulations and in an amount sufficient to cover the costs, as specified pursuant to Section 1616.5. ...
- (b) Each license issued under this chapter shall expire 12 months from the date of its issuance. APPLICATION FOR LICENSE RENEWAL SHALL BE FILED WITH THE DEPARTMENT EACH YEAR NOT LESS THAN 10 DAYS PRIOR TO THE EXPIRATION EACH YEAR. FAILURE TO MAKE A TIMELY RENEWAL SHALL RESULT IN THE EXPIRATION OF THE LICENSE.

Please feel free to call Robert Hunter at (213) 620-6574 in our Los Angeles office if you have questions.