



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

November 1, 2008

ATTENTION: MEDICAL DIRECTOR

FROM: Laboratory Field Services, Biologics

SUBJECT: Biologics renewal process

This is the process for your Biologics license new or renewal. We will electronically transmit the following forms (combined):

- Fee schedule
- Biologics new or renewal application
- Biologics Personnel form

The Biologics new, renewal and personnel forms are Word fill-in forms, which may be copied, saved, and/or printed [you must unprotect the document in the tools menu]. These forms require an original signature of the Medical Director, however, and must be returned via regular mail. ***If you have had difficulty with mail delivery of your license, please include a self-addressed envelope with the renewal packet.*** These forms are being sent to the most current email addresses in our database. The LAB 118 form requires **two** current and valid email addresses. Make any corrections in the appropriate location on the personnel or renewal forms. **In addition, please do not staple or fold these forms.** If you have any questions, please do not hesitate to call or email regarding this process.

NOTE: SEND ALL DOCUMENTS, INCLUDING PAYMENTS, TO:
California Department of Public Health
320 W. 4th St., Suite 890, Los Angeles, Ca. 90013. ATTN: Bob Hunter

Robert L. Hunter, Examiner II
Ca. Department of Public Health
Laboratory Field Services
Ph (213) 620-6574
Fax (916) 341-7225
rhunter@cdph.ca.gov
<http://www.cdph.ca.gov/programs/lfs>

For your convenience we have listed the items you must include to apply or renew your Biologics License

Biologics License New or Renewal Document Check Off List

- Renewal Fee enclosed <http://www.cdph.ca.gov/programs/lfs>
– There are no additional fees for more than three collection sites
- Form Lab 175** (Biologics Renewal Form, completed and signed **original**) – please include hours of operation and 2 contact names with email * (Please add, delete, or modify off-site collection centers)
- Form Lab 114** (Biologics Application Form (if applicable), completed and signed **original**) – please include hours of operation and 2 contact names with email * - ***[New license application only]***
- Form Lab 118** (Personnel Report Form, completed and signed **original**) *
- Resume or CV for **new** physician Medical Director(s) or co-directors added since last renewal
- Cover letter from the Medical Director for physicians deleted since last renewal
- Include Biologics ID number on check
- Include all products types collected, processed, stored, or distributed in the inventory area
- Off-site collection centers** – if more than 10 are listed under one Biologics license, please email a spreadsheet which includes this information – name, address, and telephone number.
- Please see other attachments or inclusions for additional items regarding **new** blood bank, plasma, or cord/stem cell requirements

* **Forms** may also be found at

<http://www.cdph.ca.gov/pubsforms/forms/Pages/RegulatedLaboratories.aspx>

Please mail all required documents to:

**Laboratory Field Services
Biologics Program, Bob Hunter
320 W. 4th St., Suite 890
Los Angeles, CA 90013**

SUBJECT: Responsibilities of Facilities Licensed for Biologics

**HEALTH AND SAFETY CODE
SECTION 1616-1616.5**

1616. (a) Each application for a license or license renewal under this chapter shall be accompanied by a fee determined by the director by regulations and in an amount sufficient to cover the cost of administering this chapter but not to exceed those costs, as specified pursuant to Section 1616.5.

(c) Each license issued under this chapter shall expire 12 months from the date of its issuance. Application for renewal of license accompanied by the fee shall be filed with the department not less than 10 days prior to the expiration each year. Failure to make a timely renewal shall result in expiration of the license.

It is the responsibility of the Biologics facility to annually renew. Letters or email reminders are an adjunct to this process, but not required. Original license applications, renewals, or fax copies, without the accompanying fees **do not constitute** licensing or renewal. If you have any questions, do not hesitate to call or email regarding this information.

Subject: FEE SCHEDULE FOR FISCAL YEAR 2008/2009.

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 increase provisions of CHSC 100450, subdivision (a). The fee schedule for Biologics may be found @ <http://www.cdph.ca.gov/programs/lfs>.

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

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