FOOD AND DRUG BRANCH

PROCEDURE FOR OBTAINING A NEW MEDICAL DEVICE LICENSE
License Application Form: CDPH 8596

California Health and Safety Code (H&SC) Section 111615 requires manufacturers of medical devices to obtain a Medical Device Manufacturing License issued by the Department of Public Health's Food and Drug Branch (FDB). The department may require any manufacturer, wholesaler, or importer of any ophthalmic device in this state to obtain a license.

License Application

Submit a fully completed Medical Device Manufacturing License Application form with the required fee. To obtain an application, download the CDPH 8596form from the FDB website.

Please read the application instructions on pages 3-4 of the application. Important points regarding completion of the application form:

- Include the firm name.
- Check the appropriate status box:
  - New Applicant
  - Relocation
  - Ownership Change
  - Ownership and Location Change
- The business address must be that of the manufacturing plant, not that of the corporate headquarters.
- The mailing address can be that of the plant, corporate headquarters or the firm's branch office. Licenses and renewal notices will be sent to the mailing address listed on the application form.
- Proper telephone numbers must be provided to expedite scheduling of inspection appointments.
- Include with the license application, evidence of ownership and any one of the following:
  - A copy of a valid biologics license issued by the FDA, or
  - A copy of a valid establishment registration pursuant to Section 510 of the federal act ***and*** an attestation that a federal inspection was completed within the last two years, or
  - Documentation demonstrating compliance to International Organization for Standardization (ISO) standards (ISO 9000 series, ISO 13485:2003, ISO 15378:2006)
  - A copy of an approved investigational device exemption

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Here is what you can do for the Evidence of Ownership submission:

- Go to the Secretary of State's website where the corporation was incorporated in and perform a business entity search.

- Print out the document with the Corporate or LLC information on it and send it along with your application. If you have had an inspection by the FDA or have ISO 9000 series, ISO 13485:2003, ISO 15378:2006 certification, then send in a copy of the certification or inspection. If you have not had an FDA inspection or ISO certification, then do not send anything regarding that issue. If you have not had an FDA inspection and you have not been ISO certified, then we will most likely conduct our own inspection of your facility. Thank you.

Any incomplete and/or illegible applications will be RETURNED to the applicant. **License fees are non- refundable.** Medical Device Licenses are non-transferrable to new owners or other locations. A change in ownership or a change in facility location will require submittal of a NEW application.

The first Medical Device Manufacturing License that is issued after an inspection or an AB1277 department approval is valid for one year. Thereafter, licenses are renewed every two years. It is your responsibility to renew the license prior to the expiration date printed on the license. You will receive a renewal notice from FDB approximately two months before the expiration date of your license. Follow the instructions on the renewal notice and submit the completed application form, a check or money order, and any required documentation. If you do not receive a renewal notice, please contact the Medical Device Safety Desk email at FDBMedDevice@cdph.ca.gov