



## FOOD AND DRUG BRANCH



### PROCEDURE FOR OBTAINING A NEW MEDICAL DEVICE LICENSE License Application Form: CDPH 72N

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, you may call FDB at (916) 650-6500 or download the form from the FDB website (<http://www.cdph.ca.gov/programs/Pages/fdbMedDevProgram2012.aspx> ; click "Form 72N.")

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 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

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 New Medical Device Manufacturing License is valid for one year. 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 at (916) 650-6500.