

State of California Inspections

Overview and Current Trends

James Barquest, PhD
Ground Zero Pharmaceuticals
Irvine, CA

SoCalBio Regulatory Workshop

State Authority

- Sherman Food, Drug and Cosmetic Law – California Health and Safety Code Section 109875 et seq.
- Devices and Drugs
- Enforced by Food and Drug Branch, California Department of Public Health

Sherman FD&C Law

- Adulteration
- Misbranding
- False advertising
- New drugs and devices
- Manufacturer licensing
- Home Medical Device Retail Facility Licensing

Federal Preemption

- Drug
- Device
 - FDA granted CA petition for exemption from preemption

Relationship with the FDA

- Information Sharing
- MOU
- Partnering
- Inspection Contracts
- Recognition of federal product approvals (BLA, NDA, PMA, 510(k))
- Adoption of key federal regulations
- Performance standards

Duplication of FDA

- Workload
 - Regular planning
 - State Investigators are commissioned by FDA
- Mutual recognition
 - Federal use of State inspection information
 - State use of FDA inspection information (Sherman)
 - Use of third party inspection information (Sherman)

Manufacturer Licensing

- HSC 111615 - **No person shall manufacture any drug or device in this state unless he or she has a valid license from the department.** The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable. The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license.

Manufacturer Licensing

- HSC 109970 - "Manufacture" means the **preparation, compounding, propagation, processing, or fabrication** of any food, drug, device, or cosmetic. The term "manufacture" includes **repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic** in furtherance of the distribution of the food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

Manufacturer Licensing

- Importer/Distributor
- Specification developer
 - Device
 - Drug

Manufacturer Licensing

- HSC 109920 - "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, **including any component, part, or accessory**, that is any of the following (a) Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them; (b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal; (c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Drug/Device Manufacturer Licensing

- Components
- Spec Developers
- Fees
 - New (\$1600 – good for one year)
 - Renewal (\$2600 - biennial fee)
- Federal GMPs

State Inspection Authority

- Entry and inspection
- Access to records
 - Financial
 - Personnel
 - Research
- Investigators have peace officer status
- Embargo
- Samples

License Inspection Coverage

- GMPs
 - QSIT (device)
- Product approvals
- Registration, listing
- General requirements of the Sherman Law

Important State Differences

- Licensing of investigational product manufacturing
- Licensing of component manufacturers
- License required before product can be distributed (both investigational and commercial)

Manufacturer Licensing Process

- Submit application at least 90 days prior to readiness for inspection
 - Fee
 - Application good for 1 year
- Assigned investigator will contact and arrange for inspection
- GMP inspection performed
 - Notice of violation
 - Firm response
 - Re-inspection if necessary

Manufacturer Licensing Process

- Licensing recommendation
- Licensing
 - May not ship prior to licensing
- License good for 1 year; inspection not always performed prior to biennial renewal

Export Documents

- Export certificates may be issued upon request of licensed firms in good standing
 - Label review
- Fees
 - Initial (\$101.71)
 - Certificate (\$25 each)

Home Medical Device Retail Facility Licensing

- HSC 109948. (a) "Home medical device retail facility" is an area, place, or premises, other than a licensed pharmacy, in and from which **prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription.** "Home medical device retail facility" includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.

HMDRF Licensing

- In-state
- Out of State
- Exemptee
- Fees
 - California (\$850 per year; \$425 warehouse only)
 - Out of State (\$150 per year)
 - Exemptee
 - New (\$250 – good for 1 year)
 - Renewal (\$150 per year)

For More Information

- California Statutes
<http://www.leginfo.ca.gov/calaw.html>
- California Regulations
<http://www.oal.ca.gov/ccr.htm>
- Device Licensing Information/Applications
<http://www.cdph.ca.gov/certlic/device/Pages/MedicalDeviceSafety.aspx>
- Drug Licensing Information/Applications
<http://www.cdph.ca.gov/certlic/manfprocdistrib/Pages/Drug.aspx>

For More Information

- State Telephone Directory

http://www.cold.ca.gov/state_employees.asp

State of California Inspections

Overview and Current Trends

James Barquest, PhD
Ground Zero Pharmaceuticals
Irvine, CA