

Title 17 Code of California Regulations (CCR)

Sections §10376, §10377, and §§10377.1 thru 10377.8

Cal. Admin. Code tit. 17, § 10376

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Title 17. Public Health

Division 1. State Department of Health Services (Refs & Annos)

Chapter 5. Sanitation (Environmental) (Refs & Annos)

Subchapter 2. Foods and Drugs

Group 1. Rules and Regulations

Article 2. Drugs and Devices Regulations

§ 10376. Drug and Device Manufacturing Licenses.

- (a) The fee for a manufacturer's license as required by Sections 26685 and 26688 of the Health and Safety Code is \$200.00 and will cover a period of 12 months. The license is not transferable and will not be prorated.
- (b) Manufacturers of human prescription drugs shall pay an additional license fee of \$100.00 per year, plus the fingerprint processing fee charged by the California Department of Justice.
- (c) Application for Drug Manufacturing License shall be made on State Department of Health form #EH-52 (Rev. 4/93). Applications for a Device Manufacturing License shall be made on State Department of Health form #EH-72.
- (d) Applications for a Drug Manufacturing License shall include the following information on or attached to the application form:
- (1) The name of the license applicant, and the full business address and telephone number of the manufacturing facility;
 - (2) All trade or business names used by the license applicant;
 - (3) Name(s) of the person(s) in charge of manufacturing;
 - (4) Name, address and telephone number of the person responsible for correspondence;
 - (5) The type of ownership or operation (for example, partnership, association, corporation, or individual/sole proprietorship);
 - (6) The name(s) of the owner and/or operator of the license applicant, including:
 - (A) If an individual, the name of the individual; if a sole proprietorship, the name of the sole proprietor and the name of the business entity;
 - (B) If a partnership or other unincorporated association, the name of each partner or member, and name of the partnership or association;

(C) If a corporation, the corporate name, and the state of incorporation, the name and title of each corporate officer and director; and

(D) The name of each person holding more than 5 percent equity, or debt liability of the applicant.

(7) Types of products to be manufactured;

(8) Type of processing to be utilized;

(9) Signature of license applicant under penalty of perjury affirming that the information in the application is true and accurate;

(10) Printed name and title of the individual signing the application;

(11) Date application was signed; and

(12) For human prescription drug manufacturers only:

(A) properly completed Disclosure Statement (form #EH-53 (rev. 4/93)), two properly completed fingerprint cards, and fingerprint processing fee for each person in charge of manufacturing and each person whose name is required to be included in the license application under Paragraphs (d)(6)(A) through (d)(6)(C). However, where the license applicant is a corporation, partnership, or other business association and the total number of partners, members, or corporate officers, directors, and shareholders (as the case may be) exceeds five, the application shall so state, and the documents and fee described in this Paragraph shall only be submitted for each person in charge of manufacturing, and

1. For corporations: of the corporate officers who reside in California, or who reside outside California, but are involved in the routine operations of the manufacturing facility, the documents and fee shall be submitted for each of the five highest ranking officers in this group, and

2. For partnerships, joint ventures, and similar business association: of the partners or members who reside in California, or who reside outside California, but are involved in the routine operations of the manufacturing facility, the documents and fee shall be submitted for each of the five persons in this group who own the largest interests in the applicant entity.

(B) Fingerprint cards and fingerprint processing fee shall only be submitted once for each person. If there is a change of any person in charge of manufacturing or any person occupying a position listed in Paragraphs (d)(6)(A) through (d)(6)(C), fingerprint cards and processing fee shall be submitted for each new or additional person.

(C) Other persons listed in Paragraph (d)(6) may be required by the Department to submit the documents described in this Paragraph as necessary to determine the qualifications of the applicant.

(e) Within 30 calendar days of receipt of a drug manufacturing license application, the Department shall inform the applicant in writing that it is both complete and accepted for filing or that the application is deficient and what specific information or documentation is required to complete the application. An

application is considered complete when all information, documents, and fees required in this Section have been received by the Department.

(f) Within 240 calendar days from the date of filing of a completed drug manufacturing license application, the Department shall inform the applicant in writing of its decision regarding a drug manufacturing license application. The median time for the Department to process a drug manufacturing license application from acceptance of the initial application to the final license decision has been 29 calendar days; the minimum time was one calendar day; the maximum time was 919 calendar days.

§ 10377. Definitions.

(a) The definitions set forth in this Section apply to Sections 10376 through 10377.8 only.

(b) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(c) Blood component means that part of blood separated by physical or mechanical means.

(d) Controlled Substance means, unless otherwise specified, a drug, substance, or immediate precursor which is listed in any schedule in Health and Safety Code Sections 11054, 11055, 11056, 11057, or 11058, or which is regulated as a controlled substance under the Controlled Substances Act (21 U.S.C. s 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. s 951 et seq.).

(e) Drug sample means a unit of a human prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(f) Human prescription drug means any drug intended for human use required by State law to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 26660 of the Health and Safety Code.

(g) Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man, including those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(h) Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in the drug product.

(i) Manufacturer means any person who prepares, compounds, propagates, processes, or fabricates any drug. The term manufacturer includes anyone who repackages or otherwise changes the container, wrapper, or labeling of any drug in furtherance of the distribution of the drug. The term manufacturer does not include:

(1) A retailer who repackages from a bulk container at the time of sale to its ultimate consumer; or

(2) Anyone who sells, purchases, or trades blood or blood components intended for transfusion, provided that the blood or blood components are prepared using physical or mechanical means, not chemical processes.

(j) Transfusion means a use of blood or blood components in which the blood or blood components are administered into a vein of a human being for treatment of disease, including physical injury.

§ 10377.1. Qualifications.

(a) A license to manufacture human prescription drugs may be denied on the ground that the license applicant is not qualified by reason of the applicant's experience to manufacture and distribute human prescription drugs in a safe manner and in compliance with federal, state, and local drug laws. In the case of a partnership, association, or corporation, an applicant's experience includes the experience of each person whose name is required to be included in the license application. An applicant's experience includes, but is not limited to, the following factors:

(1) Any conviction of the applicant under any federal, state, or local laws relating to drugs, including drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony conviction of the applicant under federal, state, or local laws which is substantially or rationally related to the qualifications, functions, and duties of a licensed human prescription drug manufacturer; a crime shall be considered substantially or rationally related to qualifications, functions, or duties of human prescription drug manufacturer if, reasonably or to a substantial degree, it evidences present or potential unfitness of a licensee to perform the functions authorized by the license in a manner consistent with the public health, safety, or welfare.

(3) The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under drug or device licenses previously granted by the Department, if any;

(7) Compliance with requirements to maintain and/or make available to the Department those records required under the Sherman Food, Drug, and Cosmetic Law (Health and Saf. Code s 26000 et seq.) and the regulations adopted pursuant to that law;

(8) Compliance with requirements to make available to federal, state, or local law enforcement officials those records described in 21 Code of Federal Regulations section 205.50 (55 Fed. Reg. 38025-38026 (Sept. 14, 1990)); and

(9) History of addiction or habitual use of any controlled substance, narcotic, prescription drug, or alcoholic beverage.

(b) As used in subsection (a), "conviction" includes a plea, verdict, or finding of guilt regardless of whether sentence has been imposed, but does not include:

(1) any conviction for an offense specified in subdivision (a) or (b) of Health and Safety Code Section 11361.5 which became final more than two years prior to the date of the license application, or

(2) any conviction under Health and Safety Code Section 11557 or its successor Section 11366 when that conviction was stipulated or designated to be a lesser included offense of the offense of possession of marijuana;

(c) The Department may deny a license to a license applicant if it determines that the granting of such a license would not be in the public interest, based on factors which are substantially or rationally related to protecting the public from adulterated or misbranded human prescription drugs.

§ 10377.2. Revocation and Suspension.

(a) Any conviction of any violation of federal, state, or local drug laws shall be grounds for suspending or revoking a license to manufacture human prescription drugs.

(b) Any action or conduct which would have warranted denial of a license to manufacture human prescription drugs shall be grounds for suspending or revoking a license to manufacture human prescription drugs.

§ 10377.3. Compliance.

Human prescription drug manufacturers and their officers, agents, representatives, and employees shall comply with the requirements of Sections 10377.4, 10377.5, 10377.6, 10377.7, and 10377.8 relating to human prescription drugs.

§ 10377.4. Requirements for the Storage and Handling of Human Prescription Drugs.

(a) All facilities at which human prescription manufacturers manufacture, store, warehouse, handle, offer, market, display, or otherwise hold human prescription drugs shall be secure from unauthorized entry and shall have adequate security conditions, as follows:

(1) Access from outside the premises shall be kept to a minimum and be well-controlled;

(2) The outside perimeter of the premises shall be well-lighted; and

(3) Entry into areas where human prescription drugs are held shall be limited to authorized personnel.

(b) All such facilities shall be equipped with an alarm system to detect entry after hours.

(c) All such facilities shall be equipped with an alarm system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(d) Each outgoing shipment of human prescription drugs shall be carefully inspected for identity of the human prescription drugs and to ensure that there is no delivery of human prescription drugs that have been damaged in storage or held under improper conditions. Records of nonconforming drugs and their disposition shall be established and maintained, and shall include the name and label potency of the drug

product, dosage form, lot number, quantity, reason for nonconformance, name of the inspector, date of inspection, and disposition.

(e) Human prescription drugs manufactured by the licensee, which are outdated, damaged, deteriorated, misbranded, or adulterated, shall be quarantined and physically separated from other prescription drugs until they are destroyed or brought into compliance with all applicable laws by reprocessing or relabeling. Records of drugs quarantined shall be established and maintained, and shall include the name and label potency of the quarantined drug product, dosage form, lot number, reason for the quarantine, name of the person responsible for the quarantine, location of quarantined drug product, date of disposition, and ultimate disposition of the quarantined drug product.

§ 10377.5. Requirements for the Establishment and Maintenance of Human Prescription Drug Records.

(a) Human prescription drug manufacturers shall establish and maintain inventories and records of all transactions regarding the disposal of human prescription drugs. These records shall include the following information:

- (1) The identity and quantity of the human prescription drugs disposed of; and
- (2) The dates of disposal of the human prescription drugs.

(b) Inventories and records of receipt, distribution, disposal, and other disposition of human prescription drugs, including records described in Section 10377.4(d) and (e), shall be made available for inspection and photocopying by the Department or any authorized federal, state, or local law enforcement agency officials for a period of at least three years following distribution, disposal, or other disposition.

(c) Inventories and records of receipt, distribution, disposal, and other disposition of human prescription drugs, including records described in Section 10377.4(d) and (e), that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection as soon as possible, but no later than two working days after a request by an authorized official of a federal, state, or local law enforcement agency.

(d) Human prescription drug manufacturers shall establish and maintain lists of officers, directors, managers, and other persons in charge of human prescription drug manufacturing, distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

§ 10377.6. Written Policies and Procedures for the Handling of Human Prescription Drugs.

(a) Human prescription drug manufacturers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the security and disposition of human prescription drugs including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(b) Human prescription drug manufacturers shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of human prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to:

(A) Any action initiated at the request of the Department, the federal Food and Drug Administration or other federal, state, or local law enforcement or other government agency;

(B) Any voluntary action by the manufacturer to remove defective or potentially defective human prescription drugs from the market; or

(C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(2) A procedure to ensure that the manufacturer is prepared for, protected against, and is ready to handle any crisis that affects security or operation of any facility in the event of fire, flood, or other natural disaster, or strike or other situations of local, state or national emergency; and

(3) A procedure to ensure that any outdated human prescription drugs shall be segregated from other drugs and destroyed. This procedure shall provide for written documentation of the disposition of outdated human prescription drugs. This documentation shall be maintained for at least three years after disposition of the outdated human prescription drugs.

§ 10377.7. Inspection by Federal, State, and Local Law Enforcement Officials.

Human prescription drug manufacturers shall permit authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, during business hours or any other reasonable times and in a reasonable manner, to the extent authorized by law.

§ 10377.8. Manufacturers of Active Ingredient Components of Human Prescription Drugs.

(a) In addition to the regulations in this article, manufacturers of any active ingredient component of a human prescription drug shall comply with the following sections of Code of Federal Regulations, title 21, part 211 (revised as of April 1, 1992), except that all references to "drug product" shall apply to active ingredient components: sections 211.25 (Personnel qualifications), 211.28 (Personnel responsibilities), 211.42 (Design and construction features), 211.44 (Lighting), 211.46 (Ventilation, air filtration, air heating and cooling), 211.48(a) [first sentence] and (b) (Plumbing), 211.50 (Sewage and refuse), 211.52 (Washing and toilet facilities), 211.56 (Sanitation), 211.58 (Maintenance), 211.63 (Equipment design, size, and location), 211.65 (Equipment construction), 211.67 (Equipment cleaning and maintenance), 211.68 (Automatic, mechanical, and electronic equipment), 211.142 (Warehousing procedures), 211.150 (Distribution procedures), 211.180(a), (c), (d), and (f) (General requirements), 211.182 (Equipment cleaning and use logs), 211.196 (Distribution records), 211.204 (Returned drug products), and 211.208 (Drug product salvaging).

(b) In the event that it is impossible for a manufacturer of a biological drug to comply with both this section and the federal regulations for the manufacture of biologic drugs, this section shall not apply to the extent that it conflicts with a federal regulation specifically applicable to the biological drug product in question.