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HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] (*Division 104 added by Stats. 1995, Ch. 415, Sec. 6.*)

PART 5. SHERMAN FOOD, DRUG, AND COSMETIC LAWS [109875 - 111929.4] (*Part 5 added by Stats. 1995, Ch. 415, Sec. 6.*)

CHAPTER 2. Administration [110045 - 110243] (*Chapter 2 added by Stats. 1995, Ch. 415, Sec. 6.*)

ARTICLE 4. Export Documents [110190 - 110241] (*Article 4 added by Stats. 1995, Ch. 415, Sec. 6.*)

110190. (a) Any person who ships to another state or country a food, drug, device, or cosmetic manufactured or produced in this state may request the department to issue an export document to reference the shipment of the food, drug, device, or cosmetic. The food, drug, device, or cosmetic shall be manufactured or produced in this state by a person who has a valid registration, license, certificate, or permit issued by the department under this part or the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27). For each request, the requesting person shall submit to the department, in hardcopy or the electronic formats described in subdivision (c), all of the following:

(1) All labels, labeling, and advertising affixed to, accompanying, or relating to the food, drug, device, or cosmetic. The department shall accept electronic or paper copies of labels, labeling, or advertising.

(2) If not clearly evident from the materials submitted pursuant to paragraph (1), the requester shall submit both of the following:

(A) The name, place of business, and the type and number of the registration, license, certificate, or permit issued by the department to the manufacturer or producer of the food, drug, device, or cosmetic.

(B) The identity of the food, drug, device, or cosmetic being shipped.

(3) The name of the state or country to which the food, drug, device, or cosmetic is being shipped.

(4) The approximate date of shipment of the food, drug, device, or cosmetic.

(5) Additional statements the requesting person wishes to have incorporated into the export document.

(6) The name and telephone number of the requesting person to whom the department may refer questions or requests for additional information.

(b) The person making the request shall also submit the one-time fee required by paragraph (1) of subdivision (a) of Section 110210, if the fee has not yet been paid, and the minimum charge required by paragraph (2) of subdivision (a) of Section 110210.

(c) The department shall accept requests for an export document submitted by email or other electronic methods.

(1) For requests submitted by email or facsimile on or after January 1, 2014, payment of the fees described in subdivision (b) shall be provided to, and received by, the department within five business days after submittal of the request. The department shall suspend processing of a request if payment is not received within five business days, and shall resume processing once it receives the payment.

(2) For requests submitted using an electronic document request submittal process developed by the department and available on the department's Internet Web site, payment shall be submitted at the time of the request.

(d) The department shall develop procedures to expedite approval of requests for an export document in which the labels, labeling, and advertising affixed to, accompanying, or relating to the food, drug, device, or cosmetic remain unchanged from a previously approved request for an export document for that food, drug, device, or cosmetic.

110200. (a) Each export document issued by the department shall do all of the following:

(1) Identify either or both of the following:

(A) The name and place of business of the manufacturer or producer of the food, drug, device, or cosmetic.

(B) The name and place of business of the distributor of the food, drug, device, or cosmetic.

(2) Identify the food, drug, device, or cosmetic being shipped.

(3) Identify the state or country to which the food, drug, device, or cosmetic is being shipped.

(4) Identify the approximate date of shipment.

(5) Describe the department's authority over the food, drug, device, or cosmetic to be shipped and its manufacturer or producer.

(6) State that the department does not object to the sale of the food, drug, device, or cosmetic in this state or the shipment of the food, drug, device, or cosmetic to any other state or country.

(b) Each export document issued by the department may, in the department's sole discretion, include additional statements requested by the person who requested the export document.

(c) Each export document issued by the department shall be issued by the Chief of the Food and Drug Branch of the department, or his or her designee. The chief or his or her designee may issue an export document prepared by the department or by the requesting person.

(d) The export document shall expire one year after its issue date.

(Amended by Stats. 2013, Ch. 539, Sec. 2. (AB 1400) Effective January 1, 2014.)

110210. (a) Each person requesting the department to issue an export document shall pay nonreturnable fees as follows:

(1) A one-time fee of one hundred dollars (\$100).

(2) A fee for service charge at the rate of eighty dollars (\$80) per hour, at a minimum of twenty-five dollars (\$25) per request.

(3) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.

(b) The fee amounts shall be adjusted annually pursuant to Section 100425.

(c) In no case shall the fees exceed the reasonable costs of the department in administering this article.

(d) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110220. (a) The department may refuse to accept any request where the information required to be submitted by this article is incomplete.

(b) The department may refuse to issue an export document, or may invalidate an export document, if it finds, or has probable cause to believe, any of the following:

(1) The food, drug, device, or cosmetic, or requesting person violated any provision of this part, the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27), or any regulation adopted pursuant to this part or that act.

(2) Any information required to be submitted by this article is incomplete or false.

(3) The requesting person has not paid all outstanding fees required by this article.

(4) The food, drug, device, or cosmetic is not manufactured or produced in this state.

(5) The food, drug, device, or cosmetic is intended to be exported under Section 110655, 110790, 111315, 111460, 111720, or 111785.

(6) The food is a raw agricultural commodity or dairy product regulated by the Department of Food and Agriculture or a poultry or meat product regulated by the United States Department of Agriculture.

(c) If the department refuses to issue an export document, or invalidates an export document, the department shall inform the requesting person in writing of the reasons for the refusal or invalidation. The requesting person may request reconsideration by forwarding a written request to the Chief of the Division of Environmental Health of the department. The request for reconsideration must be postmarked or received by the department no later than 30 days after the date of the department's refusal or invalidation, and shall include a complete statement of all arguments and evidence that support the request for reconsideration. The Chief of the Division of Environmental Health shall notify the requesting person of his or her decision within 30 days. The decision of the Chief of the Division of Environmental Health shall be final.

(d) It is the intent of the Legislature that the department shall respond to each request for issuance of an export document within five working days of receipt of the request by the Food and Drug Branch of the department.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110225. It is unlawful for any person to knowingly supply the department with false material facts in a request for an export document or to falsely represent that the department has issued an export document.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110230. Any person who has a valid registration, license, certificate, or permit issued by the department to manufacture or produce a food, drug, device, or cosmetic in this state may request the department to issue an official copy of the valid registration, license, certificate, or permit.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110235. (a) Each person requesting the department to issue an official copy of a valid registration, license, certificate, or permit shall pay nonreturnable fees as follows:

(1) Fifteen dollars (\$15) per official copy.

(2) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.

(b) The fee amount shall be adjusted annually pursuant to Section 100425.

(c) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110240. There is established an Export Document Program Fund within the General Fund. All fees collected pursuant to Sections 110210 and 110235 shall be deposited into the Export Document Program Fund and, upon appropriation, shall be expended by the department for the purpose of administering this article.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110241. All fees collected by the department pursuant to requests to conduct a voluntary medical device review shall be deposited into the Export Document Program Fund and, upon appropriation, shall be expended for the purpose of determining if the device is a new device or is substantially equivalent to a current or previously marked device.

(Added by Stats. 1997, Ch. 294, Sec. 12. Effective August 18, 1997.)