HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1796.70] *(Division 2 enacted by Stats. 1939, Ch. 60.)*

CHAPTER 4. Human Whole Blood, Human Whole Blood Derivatives, and Other Biologics [1600 - 1630] *(Chapter 4 repealed and added by Stats. 1963, Ch. 1055.)*

ARTICLE 3. Biologics Other Than Human Whole Blood and Human Whole Blood Derivatives [1609 - 1611] *(Article 3 added by Stats. 1963, Ch. 1055.)*

1609. No person shall engage in the production of biologics other than human whole blood and human whole blood derivatives unless:

(a) In a laboratory licensed by the Public Health Service, United States Department of Health, Education and Welfare.

(b) In a laboratory licensed by the Animal Inspection and Quarantine Branch, Agricultural Research Service, United States Department of Agriculture.

(c) In a clinical trial site storing or preparing for patient administration biologics, other than human whole blood and human whole blood derivatives, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(d) Under the provisions of this chapter.

(Amended by Stats. 2022, Ch. 955, Sec. 2. (SB 1500) Effective January 1, 2023.)

1610. The department shall make rules and regulations governing the production of all biologics produced in establishments under subdivision (c) of Section 1609.

(Repealed and added by Stats. 1963, Ch. 1055.)

1611. The department may make rules and regulations governing the transportation or distribution of cultures of micro-organisms which may produce disease in man or animals.

(Repealed and added by Stats. 1963, Ch. 1055.)