

Amend SB 943 (House Committee Report) as follows:

(1) In SECTION 2 of the bill, in amended Section 431.4031, Health and Safety Code (page 7, line 4), strike "431.4045" and substitute "431.4045(2)".

(2) In SECTION 4 of the bill, in added Subdivision (1), Section 431.4045, Health and Safety Code (page 10, line 22), between "431.404" and the underlined semicolon, insert the following:

or determines that an inspection is unnecessary after thoroughly evaluating the information in the application, the compliance history of the applicant and the applicant's principals, and the risk of counterfeiting in the applicant's product

(3) In SECTION 5 of the bill, in amended Section 431.405, Health and Safety Code (page 11, line 1), strike "To" and substitute the following:

(a) The department may not issue a wholesale distributor license to an applicant without considering the minimum federal information and related qualification requirements published in federal regulations at 21 C.F.R. Part 205, including:

(1) factors in reviewing the qualifications of persons who engage in wholesale distribution, 21 C.F.R. Section 205.6;

(2) appropriate education and experience for personnel employed in wholesale distribution, 21 C.F.R. Section 205.7; and

(3) the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records, 21 C.F.R. Section 205.50.

(b) In addition to meeting the minimum federal requirements as provided by Subsection (a), to [~~To~~]

(4) In SECTION 5 of the bill, in amended Subdivision (6), Section 431.405, Health and Safety Code (page 11, line 20), between "in a circumstance" and "in which", insert ", as the department determines reasonable,".