

§ 808.55

§ 808.55 California.

(a) The following California medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration exempted them from preemption under section 521(b) of the act: Business and Professions Code sections 3365 and 3365.6.

(b) The following California medical device requirements are preempted by section 521 of the act, and FDA has denied them an exemption from preemption:

(1) Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code), sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26641, to the extent that they apply to devices.

(2) Sherman Food, Drug, and Cosmetic Law, section 26463(m) to the extent that it applies to hearing aids.

(3) Business and Professions Code section 2541.3, to the extent that it requires adoption of American National Standards Institute standards Z-80.1 and Z-80.2.

[45 FR 67324, Oct. 10, 1980]

§ 808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20-403 and 20-404.

[45 FR 67336, Oct. 10, 1980]

§ 808.59 Florida.

The following Florida medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(a) Florida Statutes, section 468.135(5).

(b) Florida Administrative Code, section 10D-48.25(26).

[45 FR 67336, Oct. 10, 1980]

§ 808.61 Hawaii.

(a) The following Hawaii medical device requirements are enforceable not-

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withstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Hawaii Revised Statutes, chapter 451A, §14.1, subsection (a) with respect to medical examination of a child 10 years of age or under, and subsection (c).

(b) The following Hawaii medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemption from preemption: Hawaii Revised Statutes, chapter 451A, §14.1, subsection (a) to the extent that it requires a written authorization by a physician and does not allow adults to waive this requirement for personal, as well as religious reasons, and subsection (b).

[50 FR 30699, July 29, 1985; 50 FR 32694, Aug. 14, 1985]

§ 808.67 Kentucky.

The following Kentucky medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

[45 FR 67336, Oct. 10, 1980]

§ 808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-C, on the condition that, in enforcing this requirement, Maine apply the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

(b) The following Maine medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-D and the last sentence of section 1658-E.

[45 FR 67336, Oct. 10, 1980]