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576-01397-16

Proposed Committee Substitute by the Committee on Appropriations (Appropriations Subcommittee on General Government)

A bill to be entitled

An act relating to cosmetic product registration; amending s. 499.015, F.S.; removing the requirement that a person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state must register such cosmetic biennially with the Department of Business and Professional Regulation; amending ss. 499.003, 499.041, and 499.051, F.S.; conforming provisions to changes made by this act; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and~~,~~ devices~~, and cosmetics~~; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or~~,~~ device~~, or cosmetic~~ in this state must register such drug or~~,~~ device~~, or cosmetic~~ biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or~~,~~ device~~, or cosmetic~~ at the time of registration.

(b) The department may not register any product that does

not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or~~,~~ devices~~, and cosmetics~~ packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and~~,~~ devices~~, and cosmetics~~, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or~~,~~ device~~, or cosmetic product~~. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or~~,~~ device~~, or cosmetic product~~ to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the

date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or~~,~~ devices~~, or cosmetics~~ covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer’s medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application

for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and ~~Federal~~ Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and ~~Federal~~ Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and ~~Federal~~ Drug Administration, a federal Food and ~~Federal~~ Drug Administration registration number.

Section 2. Subsection (6) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug or~~,~~ device~~, or cosmetic,~~ that is registered with the department~~,~~ as one that can be legally sold in the state.

Section 3. Subsection (6) of section 499.041, Florida Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale

certificates.—

(6) A person that is required to register drugs or~~,~~ devices~~, or cosmetic products~~ under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

Section 4. Subsection (2) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or cosmetic ~~product~~.

Section 5. For the 2016-2017 fiscal year, the sum of $222,564 in recurring funds is appropriated from the General Revenue Fund to the Division of Drugs, Devices, and Cosmetics in the Department of Business and Professional Regulation for the purpose of implementing this act, and the appropriation from the Professional Regulation Trust Fund to the division shall be reduced by $222,564.

Section 6. This act shall take effect July 1, 2016.