

By the Committee on Regulated Industries; and Senator Brandes

580-01939-15

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1 A bill to be entitled

2 An act relating to cosmetic product registration;  
3 amending s. 499.015, F.S.; removing the requirement  
4 that a person who manufactures, packages, repackages,  
5 labels, or relabels a cosmetic in this state must  
6 register such cosmetic biennially with the Department  
7 of Business and Professional Regulation; amending ss.  
8 499.003, 499.041, and 499.051 F.S.; conforming  
9 provisions to changes made by this act; providing an  
10 effective date.

11  
12 Be It Enacted by the Legislature of the State of Florida:

13  
14 Section 1. Section 499.015, Florida Statutes, is amended to  
15 read:

16 499.015 Registration of drugs and, devices, ~~and cosmetics~~;  
17 issuance of certificates of free sale.-

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

27 (b) The department may not register any product that does  
28 not comply with the Federal Food, Drug, and Cosmetic Act, as  
29 amended, or Title 21 C.F.R. Registration of a product by the

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30 department does not mean that the product does in fact comply  
31 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
32 as amended.

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

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

52 (4) Unless a registration is renewed, it expires 2 years  
53 after the last day of the month in which it was issued. The  
54 department may issue a stop-sale notice or order against a  
55 person that is subject to the requirements of this section and  
56 that fails to comply with this section within 31 days after the  
57 date the registration expires. The notice or order shall  
58 prohibit such person from selling or causing to be sold any

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59 drugs or devices, ~~or cosmetics~~ covered by this part until he or  
60 she complies with the requirements of this section.

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

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

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

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

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

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

84 (9) However, the manufacturer must submit evidence of such  
85 registration, listing, or approval with its initial application  
86 for a permit to do business in this state, as required in s.  
87 499.01 and any changes to such information previously submitted

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88 at the time of renewal of the permit. Evidence of approval,  
89 listing, and registration by the federal Food and Drug  
90 Administration must include:

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

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

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

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

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

105 499.003 Definitions of terms used in this part.—As used in  
106 this part, the term:

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

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

113 499.041 Schedule of fees for drug, device, and cosmetic  
114 applications and permits, product registrations, and free-sale  
115 certificates.—

116 (6) A person that is required to register drugs or

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117 devices, ~~or cosmetic products~~ under s. 499.015 shall pay an  
118 annual product registration fee of not less than \$5 or more than  
119 \$15 for each separate and distinct product in package form. The  
120 registration fee is in addition to the fee charged for a free-  
121 sale certificate.

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

124 499.051 Inspections and investigations.—

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

131 Section 5. This act shall take effect July 1, 2015.