The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on General Government

BILL:	PCS/SB 176 (449874)
INTRODUCER:	Appropriations Subcommittee on General Government and Senator Brandes
SUBJECT:	Cosmetic Product Registration
DATE:	November 20, 2015 REVISED: 1/4/16

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kraemer	Imhof	RI	**Favorable**
2.	Davis	DeLoach	AGG	**Recommend: Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

The Department of Business and Professional Regulation (DBPR or department), Division of Drugs, Devices, and Cosmetics (division), regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida are required to hold an active cosmetic manufacturer permit issued by the division. Each product produced or repackaged by such manufacturers is required to be registered with the division. New cosmetic products and identical products are currently registered every two years.

PCS/SB 176 amends ch. 499, F.S., to eliminate the requirement that Florida cosmetic manufacturers register cosmetic products with the division. The bill removes registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees. The bill also removes the division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

The bill appropriates $222,564 in recurring funds from the General Revenue Fund in Fiscal Year 2016-2017 to the division for the implementation of this act, and reduces funding for the division from the Professional Regulation Trust Fund by the same amount.

II. Present Situation:

State and Federal Regulation

Section 499.003(12), F.S., defines "cosmetic" as an article other than soap, which is either:

- Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance; or
- Intended for use as a component of the article.

The regulation of cosmetics is addressed in ch. 499, F.S., which regulates drugs, devices, and cosmetics by the department.[1] The Florida Drug and Cosmetic Act (the act),[2] is intended to safeguard public health and promote public welfare by protecting against injuries and merchandising deceit involving drugs, devices, and cosmetics or the use of such products. Currently, cosmetics manufactured outside of Florida are not required to be registered with the division.

Administration of the act must conform to the Federal Food, Drug, and Cosmetic Act (the federal act)[3] and the applicable portions of the Federal Trade Commission Act[4] which prohibit the false advertising of drugs, devices, and cosmetics. According to an industry representative, eight billion personal care products are sold in the United States annually, constituting over $60 billion in annual sales.[5]

The act authorizes the division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida. Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the division. Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[6] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers. A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[7]

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[1] The Drug, Device, and Cosmetic program was transferred to the Department of Business and Professional Regulation from the Department of Health effective November 1, 2012. *See* ch. 2012-184, L.O.F., s. 122, at http://laws.flrules.org/2012/184 (last visited Nov. 2, 2015) and ch. 2012-143, L.O.F., s. 3, at http://laws.flrules.org/2012/143 (last visited Nov. 2, 2015).
[2] *See* ss. 499.001-499.081, F.S.
[3] Section 499.003(20), F.S., defines the federal act referencing 21 U.S.C. ss. 301 *et seq.* and 52 Stat. 1040 *et seq*.
[4] *See* 15 U.S.C. §§ 41-58, as amended.
[5] Conversation with John Ray on behalf of the Florida Cosmetics Manufacturers Coalition (November 12, 2014).
[6] Florida Department of Business and Professional Regulation, *Cosmetic Manufacturer,* accessible at http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last viewed November 13, 2015).
7 Section 499.01(2)(o), F.S.

Florida law requires any person who manufactures, packages, repackages, labels, or relabels a cosmetic in Florida to register "each separate and distinct" cosmetic every two years.[8] .[9] New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[10] The registration and biennial renewal fee for cosmetic products is $30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer. For example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The DBPR requires by rule that the different variations be listed and registered on an Identical Product Certification form.[11] The process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[12]

Because registration is a prerequisite to sales of a cosmetic, Florida's registration system is a pre-market reporting system that is handled by the division.[13] This is in contrast with the system of the United States Food and Drug Administration (FDA), which is a post-market reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States.[14] Under the FDA's system, any representation in labeling or advertising that creates an impression of official approval because of registration or possession of a registration number is considered misleading. Misleading labeling makes a cosmetic misbranded, and marketing a misbranded cosmetic violates federal law.[15] Enforcement of the federal act is initiated by a complaint by a consumer, which may be accomplished by mail, fax, through their health provider, pharmacist, or via an online report.[16] The division, in a "Helpful Links and Resources" section on its website,[17] provides a link to the FDA website.

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[8] *See* s. 499.015, F.S., and Application for Product Registration - Cosmetics (Main & Identical), Form No.: DBPR-DDC-228 at http://www.myfloridalicense.com/dbpr/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last accessed Nov. 2, 2015).
[9] *See* s. 499.015, F.S., and Application for Product Registration - Cosmetics, Form No.: DBPR-DDC-228 at http://www.myfloridalicense.com/dbpr/ddc/documents/ProductRegistrationCosmetics.pdf (last accessed Mar. 3, 2015).
[10] Rule 61N-1.016(4)(b), F.A.C.
[11] *See* Rule 61N-1.016(1)(b), F.A.C., and Application for Identical Product Registration, Form No.: DBPR-DDC-230 at http://www.myfloridalicense.com/dbpr/ddc/documents/IdenticalProductRegistration.pdf (last accessed Mar. 3, 2015).
[12] Rule 61N-1.016(1)(b), F.A.C.
[13] *See* http://www.myfloridalicense.com/dbpr/ddc/index.html (last visited Mar. 3, 2015).
[14] *See* the FDA's description of its Voluntary Cosmetics Registration Program and its benefits at http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited Nov. 2, 2015). The program does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics, nor to products that are not for sale, such as hotel samples, free gifts, or cosmetic products made at home and given to family and friends.
[15] *Id.*
[16] *See* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm354560.htm (last visited Nov. 2, 2015).
[17] *See* http://www.myfloridalicense.com/dbpr/ddc/ddc_helpful_links.html (last visited Nov. 2, 2015).

Renewal Registrations

For renewal of a product registration, an applicant must submit product labels, an Application for Product Registration Renewal, and the required fee.[18] According to the division, cosmetic product renewals are not reviewed by the department for compliance with the FDA's regulations where the cosmetic products were "initially reviewed, compared with the FDA regulations, and approved for registration with the division."[19]

Certificates of Free Sale

The department issues certificates of free sale (COFS)[20] for a fee of $25 to certify that a cosmetic that is registered with the department may be legally sold in Florida. A COFS is required by many foreign countries before a product may be sent into the country. A COFS need not be obtained from the department, but may be obtained from the FDA,[21] and other organizations, including the Miami Beach Chamber of Commerce.[22]

III. Effect of Proposed Changes:

The bill removes the requirement that Florida cosmetic manufacturers register cosmetic products with the division. In addition, the bill makes conforming changes by removing registration and renewal requirements for cosmetic products including the requirements to submit registration applications, product labels, and registration and renewal fees. The bill allows Florida cosmetic manufacturers' products to be treated the same as cosmetic products manufactured outside of Florida that are distributed and sold in the state.[23]

The bill also eliminates the authorization to the department to issue a "certificate of free sale" certifying that a cosmetic is registered with the department and may be legally sold in Florida.[24]

In addition, the bill appropriates $222,564 in recurring funds from the General Revenue Fund in Fiscal Year 2016-2017 to the division for the implementation of this act, and reduces funding for the division from the Professional Regulation Trust Fund by the same amount.

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[18] *See* Rule 61N-1.016(3), F.A.C., and Form DBPR-DDC-235, at https://www.flrules.org/Gateway/reference.asp?No=Ref-05666 (last accessed Nov. 2, 2015).
[19] *Id*. at paragraph 4.
[20] Section 499.041(7), F.S., uses the term "free-sale certificate," and imposes a fee of $25, with $2 for each copy obtained at the same time that the certificate is issued by the department.
[21] *See* http://www.fda.gov/Cosmetics/InternationalActivities/Exporters/ucm129593.htm#Are_there_other (last visited Nov. 2, 2015).
[22] According to the FDA, some foreign governments accept certificates issued by a state or local health department, board of trade, or trade association. Due to limited resources, the FDA recommends that firms pursue such alternative sources for export certificates whenever possible, provided they are acceptable to the country requiring a certificate. *See* http://www.fda.gov/Cosmetics/InternationalActivities/Exporters/ucm129593.htm#Are_there_other (last visited Nov. 2, 2015). These online sites offer certificates of free sale services: http://icmad.org/programs/certificates-of-free-sale (last visited Nov. 2, 2015), http://www.personalcarecouncil.org/member-industry-resources/certificates-free-sale (last visited Nov. 2, 2015), and http://www.miamibeachchamber.com/Certificate-of-Free-Sale.php (last visited Nov. 2, 2015).
[23] *See 2016 Department of Business and Professional Regulation Legislative Bill Analysis for SB 176*, September 29, 2015 (on file with Senate Appropriations Subcommittee on General Government) on page 2.
[24] *See* s. 499.003(6), F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

PCS/SB 176 eliminates fees for cosmetic product registrations and renewals, as well as fees for the issuance of certificates of free sale for cosmetic products.

B. Private Sector Impact:

The bill has a positive fiscal impact for cosmetic manufacturers due to the elimination of the fees associated with product registration and renewal. The elimination of premarket registration requirements in Florida may require manufacturers, who have relied upon issuance by the department for certificates of free sale, to obtain that service from third parties.

C. Government Sector Impact:

The DBPR estimates that the bill will reduce the annual revenue to the Drugs, Devices, and Cosmetics account within the Professional Regulation Trust Fund by $222,564[25] in Fiscal Year 2016-2017, $225,165 in Fiscal Year 2017-2018, and $227,931 in Fiscal Year 2018-2019. As a result, the loss of revenue would increase the deficit which is projected to occur in the Drugs, Devices, and Cosmetics account within the Professional Regulation Trust Fund. However, the bill appropriates $222,564 in recurring funds from the General Revenue Fund in Fiscal Year 2016-2017 to offset this expected revenue loss. The bill also reduces the appropriation from the Professional Regulation Trust Fund to the division by $222,564.

[25] The total amount of cosmetic products revenue to the Department, $222,563.70, is the sum of $165,232.50 (annual renewal fees), $45,225.00 (initial product registration fees), and $12,106.20 (fees for issuance of certificates of free sale (COFS)). *See 2016 Department of Business and Professional Regulation Legislative Bill Analysis for SB 176*, September 29, 2015 (on file with Senate Appropriations Subcommittee on General Government) at page 5.

In addition, due to the revenue reduction in the Professional Regulation Trust Fund, there will be a reduced service charge[26] amount payable to the General Revenue Fund of approximately $17,805 in Fiscal Year 2016-2017.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following the sections of the Florida Statutes: 499.015, 499.003, 499.041, and 499.051.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS by Appropriations Subcommittee on General Government on November 18, 2015:
The committee substitute provides an appropriation to the division within the DBPR for Fiscal Year 2016-2017 of $222,564 in recurring funds from the General Revenue Fund to implement the act, and reduces the appropriation to the division from the Professional Regulation Trust Fund by $222,564.

B. Amendments:

None.

[26] The service charge to the Department is 8%, representing the estimated pro rata share of the cost of general government paid from the General Revenue Fund, that is appropriated from all revenue not otherwise exempted. *See* s. 215.20, F.S. regarding the service charge, and s. 215.37, F.S., regarding the Professional Regulation Trust Fund. Section 215.37(2), F.S., provides that the regulation of professions defined in s. 455.01, F.S. be solely financed from fees and charges deposited in the Professional Regulation Trust Fund, but that each profession operate within its anticipated fees (last visited Nov. 11, 2015).