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 Committee on Regulated Industries

BILL:	SB 176
INTRODUCER:	Senator Brandes
SUBJECT:	Cosmetic Product Registration
DATE:	November 3, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kraemer	Imhof	RI	**Pre-meeting**
2.			AGG	
3.			AP	

I. Summary:

SB 176 eliminates the product registration filing requirements for each separate and distinct cosmetic product, including registrations of identical products that may differ as to color. 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.

The department estimates that elimination of the associated fees will impact the Professional Regulation Trust Fund by reducing revenue by approximately $222,563 in Fiscal Year 2016-2017, reducing payments to General Revenue by approximately $18,000 in Fiscal Year 2016-2017, and creating a deficit in the Drugs, Devices, and Cosmetics regulatory program in Fiscal Year 2016-2017.

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.

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, 8 billion personal care products are sold in the United States annually, constituting over $60 billion in annual sales.[5]

Florida law requires any person who manufactures, packages, repackages, labels, or relabels a cosmetic in Florida to register "each separate and distinct" cosmetic every 2 years.[6] The administrative rules of the department impose a $30 fee for product registrations,[7] and a fee of $15 for each identical product registration.[8] 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.[9]

This is contrasted 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.[10] 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.[11] 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.[12] The division, in a "Helpful Links and Resources" section on its website,[13] provides a link to the FDA website.

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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] *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).
[7] *See* s. 499.041, F.S.
[8] *See* Rule 61N-1.018(4)(f), F.A.C. It should be noted subsection (4) of the rule refers to "Miscellaneous OTHER fees" and does not indicate the $30 product registration fee is to be collected every 2 years (a biennial fee); references to biennial fees appear only in subsections (1), (2)(a) and (3) of the rule.
[9] *See* http://www.myfloridalicense.com/dbpr/ddc/index.html (last visited Nov. 2, 2015).
[10] *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.
[11] *Id.*
[12] *See* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm354560.htm (last visited Nov. 2, 2015).
[13] *See* http://www.myfloridalicense.com/dbpr/ddc/ddc_helpful_links.html (last visited Nov. 2, 2015).

Identical Products

The department's rules also provide that a formula marketed under different brand names, sizes, quantities, or distributors is not a separate and distinct product that must be registered.[14] The adding of color, flavor, or scents to a formula does not create a separate and distinct product for registration purposes, even for fragrance preparations where the scent is the primary product.[15] The department requires by rule that the different variations on a main product be listed and registered.[16] Section 499.015, F.S., regarding registration of cosmetics, and s. 499.041(6), F.S., regarding registration fees, which are limited to registration of "separate and distinct" products, do not address registration of identical products. The division has stated that in lieu of its rule mandating registration of identical products for a reduced fee (currently 50% of the new product registration fee of $30), it "could require each "separate and distinct" product to be registered at $30 per product."[17] Further, since each cosmetic has a label that is different, if only for the color, each cosmetic with any difference in the label is therefore a "separate and distinct" product.[18]

Renewal Registrations

For renewal of a product registration, an applicant must submit product labels, an Application for Product Registration Renewal, and the required fee.[19] According to the division, cosmetic product renewals are not reviewed by the department for compliance with the FDA's regulations because the cosmetic products were "initially reviewed, compared with the FDA regulations, and approved for registration."[20]

Certificates of Free Sale

The department issues certificates of free sale (COFS)[21] 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,[22] and other organizations, including the Miami Beach Chamber of Commerce.[23]

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[14] *See* Rule 61N-1.016(1)(b), F.A.C.
[15] *Id*.
[16] *Id*. Identical Product Registration is addressed in Form DBPR-DDC-228, Application for Product Registration - Cosmetics (Main & Identical) at http://www.myfloridalicense.com/dbpr/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last accessed Nov. 2, 2015).
[17] *See* Letter from Reginald D. Dixon, Director, Division of Drugs, Devices and Cosmetics to Florida Cosmetic Manufacturers Coalition c/o John Ray (November 26, 2014) (on file with the Senate Committee on Regulated Industries) at paragraph 5.
[18] *Id*.
[19] *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).
[20] *Id*. at paragraph 4.
[21] 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.
[22] *See* http://www.fda.gov/Cosmetics/InternationalActivities/Exporters/ucm129593.htm#Are_there_other (last visited Nov. 2, 2015).
[23] 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

III. Effect of Proposed Changes:

The bill eliminates the existing requirement that a cosmetic be registered with the Department of Business and Professional Regulation by any person who manufactures, packages, repackages, labels, or relabels a cosmetic in Florida prior to its sale.[24] The bill eliminates all registration and renewal fees for new cosmetics and for identical products.[25] The bill 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.[26]

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:

The bill 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 should have 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 of Business and Professional Regulation of certificates of free sale, to obtain that service from third parties.

C. Government Sector Impact:

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 (initial product registration fees), and

(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).

[24] *See* s. 499.015, F.S.

[25] *See* s. 499.041(6), F.S.

[26] *See* s. 499.003(6), F.S.

$12,106.20 (fees for issuance of certificates of free sale (COFS)).[27] This will increase the anticipated deficit in the separate account associated with the Drugs, Devices, and Cosmetics program division in the Professional Regulation Trust Fund (formerly the Drug, Device, and Cosmetic Trust Fund).[28] The department also notes that due to the revenue reduction, there will be a reduced service charge[29] amount payable to the General Revenue Fund of approximately $18,000 in Fiscal Year 2016-2017.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

IX. Additional Information:

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

None.

B. Amendments:

None.

[27] *See 2016 Department of Business and Professional Regulation Legislative Bill Analysis for SB 176*, September 29, 2015 (on file with Senate Committee on Regulated Industries) at pages 3-5.
[28] See ch. 2012-143, L.O.F., s. 8, at http://laws.flrules.org/2012/143 (last visited Nov. 2, 2015).
[29] 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. 2, 2015).