

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 612

INTRODUCER: Senator Brandes

SUBJECT: Cosmetic Product Registration

DATE: March 3, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Kraemer</u>	<u>Imhof</u>	<u>RI</u>	<u>Pre-meeting</u>
2.	_____	_____	<u>AGG</u>	_____
3.	_____	_____	<u>AP</u>	_____

I. Summary:

SB 612 eliminates the product registration filing requirements for each separate and distinct cosmetic product, including registrations of identical products that may differ as to color. New cosmetic products and identical products are currently registered every two years. The Department of Business and Professional Regulation estimates that elimination of the associated fees will impact the Professional Regulation Trust Fund by reducing revenue by approximately \$176,000 in Fiscal Year 2015-2016, reducing payments to General Revenue by approximately \$14,000 in Fiscal Year 2015-2016, 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 of Business and Professional Regulation (department).¹ The Florida Drug and Cosmetic Act (the act),² is intended to safeguard public health and promote public

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 Mar. 3, 2015) and ch. 2012-143, L.O.F., s. 3, at <http://laws.flrules.org/2012/143> (last visited Mar. 3, 2015).

² See ss. 499.001-499.081, F.S.

welfare by protecting against injuries and merchandising deceit involving drugs, devices, and cosmetics or the use of such products.

Further, administration of the act must conform with the Federal Food, Drug, and Cosmetic Act (the federal act)³ and the applicable portions of the Federal Trade Commission Act⁴ 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 department’s Division of Drugs, Devices and Cosmetics (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.

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, Form No.: DBPR-DDC-228 at <http://www.myfloridalicense.com/dbpr/ddc/documents/ProductRegistrationCosmetics.pdf> (last accessed Mar. 3, 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 Mar. 3, 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 Mar. 3, 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 Mar. 3, 2015).

¹³ See http://www.myfloridalicense.com/dbpr/ddc/ddc_helpful_links.html (last visited Mar. 3, 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 be listed and registered on an Identical Product Certification form.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

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."¹⁹

Certificates of Free Sale

The department issues certificates of free sale (COFS)²⁰ 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

¹⁴ See Rule 61N-1.016, F.A.C.

¹⁵ *Id.*

¹⁶ 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).

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 *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 Mar. 3, 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 Mar. 3, 2015). These online sites offer certificates of free sale services: <http://icmad.org/programs/certificates-of-free-sale> (last visited Mar. 3, 2015), <http://www.personalcarecouncil.org/member-industry-resources/certificates-free-sale> (last visited Mar. 3, 2015), and <http://www.miamibeachchamber.com/Certificate-of-Free-Sale.php> (last visited Mar. 3, 2015).

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.²³ The bill eliminates all registration and renewal fees for new cosmetics and for identical products.²⁴ 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.²⁵

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 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. The elimination of the fees associated with registration of new and identical cosmetic products will impact manufacturers based on the volume of their cosmetic registrations, renewals, and certificates of free sale.

C. Government Sector Impact:

The Department of Business and Professional Regulation (department) estimates that implementation of SB 612 will result in a revenue reduction in Fiscal Year 2015-2016 of approximately \$176,000,²⁶ which will accelerate the timeline for a deficit to occur in the

²³ See s. 499.015, F.S.

²⁴ See s. 499.041(6), F.S.

²⁵ See s. 499.003(6), F.S.

²⁶ The total amount of cosmetic products revenue to the Department, \$176,115.50, is the sum of \$93,637.50 (annual renewal fees), \$72,450.00 (initial product registration fees), and \$10,028.00 (fees for issuance of certificates of free sale (COFS)). See

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)²⁷ by Fiscal Year 2016-2017. The department also notes that due to the revenue reduction, there will be a reduced service charge²⁸ amount payable to the General Revenue Fund of approximately \$14,100 in Fiscal Year 2015-2016.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Consideration should be given to further amending ch. 499 to delete the term “cosmetic product,” in favor of the term “cosmetic.” The term “cosmetic product” is not defined in ch. 499, F.S.; but the term “cosmetic” is defined in s. 499.003(12), F.S.”

Three references to “cosmetic product” are deleted in the bill, but one remains at the end of s. 499.051(2), F.S., which provides:

(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.

VIII. Statutes Affected:

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

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.

This Senate Bill Analysis does not reflect the intent or official position of the bill’s introducer or the Florida Senate.

2015 Department of Business and Professional Regulation Legislative Bill Analysis for SB 612, February 23, 2015 (on file with Senate Committee on Regulated Industries) at pages 4-5.

²⁷ See ch. 2012-143, L.O.F., s. 8, at <http://laws.flrules.org/2012/143> (last visited Mar. 3, 2015).

²⁸ 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 Mar. 3, 2015).