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 114
INTRODUCER:	Senator Brandes
SUBJECT:	Cosmetic Product Registration
DATE:	January 24, 2017
REVISED:	

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

I. Summary:

SB 114 removes product registration filing requirements by cosmetic manufacturers for cosmetic products. The Department of Business and Professional Regulation (DBPR), Division of Drugs, Devices, and Cosmetics (division), regulates cosmetics that are manufactured and repackaged by licensed cosmetic manufacturers in Florida. Each product produced or repackaged in Florida is required to be registered with the division every two years.

The bill removes the authority of the DBPR to issue a "certificate of free sale" certifying that a cosmetic is registered with the DBPR and may be legally sold in Florida.[1]

For Fiscal Year 2017-2018, the bill is estimated to have a negative fiscal impact of $307,509 on the Professional Regulation Trust Fund within the DBPR, and a $24,601 reduction in the service charge paid to the General Revenue Fund.

The bill contains an appropriation of $222,564 in recurring funds from the General Revenue Fund for Fiscal Year 2017-2018 for implementation of the bill.

The bill provides an effective date of July 1, 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:

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

- 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 DBPR.[2] The Florida Drug and Cosmetic Act (the act),[3] 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)[4] and the applicable portions of the Federal Trade Commission Act[5] which prohibit the false advertising of drugs, devices, and cosmetics. According to a national trade association,[6] personal care products valued at $113 billion were distributed in the United States in 2013, through wholesale trade, retail trade, and personal care services,[7] with nearly 130,000 industry-related jobs located in Florida (both salaried and self-employed, including part-time).[8]

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. The term "manufacture" in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[9] 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.[10]

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.[11] New

---

[2] 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, Law of Fla., s. 122, at http://laws.flrules.org/2012/184 (last visited Jan. 21, 2017) and ch. 2012-143, Laws of Fla. s. 3, at http://laws.flrules.org/2012/143 (last visited Jan. 21, 2017).
[3] *See* ss. 499.001-499.081, F.S.
[4] 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*.
[5] *See* 15 U.S.C. §§ 41-58, as amended.
[6] The Personal Care Products Council is a national trade association representing the global cosmetic and personal care products industry, with more than 600 member companies that manufacture, distribute, and supply personal care products marketed in the United States. *See* http://www.personalcarecouncil.org/ (last visited January 21, 2017).
[7] *See Economic and Social Contributions of the US Personal Care Products Industry, 2013* (last visited January 21, 2017) at page 6.
[8] *Id*. at pages B-11 and B-12.
[9] Florida Department of Business and Professional Regulation, *Cosmetic Manufacturer,* accessible at http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last viewed Jan. 21, 2017).
10 Section 499.01(2)(o), F.S.
[11] *See* s. 499.015, F.S., and Application for Product Registration - Cosmetics (Main & Identical), Form No.: DBPR-DDC-228 at https://www.flrules.org/Gateway/reference.asp?No=Ref-05666 (last visited Jan. 21, 2017).

cosmetic products must be registered prior to sale.[12] The biennial registration fee is $30 for each cosmetic product and $15 for each identical product.[13]

Neither a formula marketed under differing brand names, sizes, quantities, or distributions, nor the adding of color, flavor, or scents to a formula, are considered to create a separate and distinct product for registration purposes. The different variations must be listed, however, pursuant to the division's administrative rules.[14] The process for identical products requires submission of an application and a $15 biennial renewal fee.[15] For renewal of a product registration, an applicant must submit product labels, an Application for Product Registration Renewal, and the required fee.[16]

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.[17] 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.[18]

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.[19] 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.[20] The division, in a "Helpful Links and Resources" section on its website,[21] provides a link to the FDA website.

Certificates of Free Sale

The DBPR issues certificates of free sale (COFS)[22] for a fee of $25 to certify that a cosmetic that is registered with the DBPR 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

[12] See Rule 61N-1.016(2), F.A.C. for requirements imposed upon applicants.
[13] *See* Rule 61N-1.018(3)(f) and (g), F.A.C.
[14] *See* Rule 61N-1.016(1)(b), F.A.C.
[15] Rule 61N-1.016(2), F.A.C.
[16] *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 visited Jan. 21, 2017).
[17] *See* http://www.myfloridalicense.com/dbpr/ddc/index.html (last visited Jan. 21, 2017).
[18] *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 Jan. 21, 2017). The program does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics, or 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.
[19] *Id.*
[20] *See* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm354560.htm (last visited Jan. 21, 2017).
[21] *See* http://www.myfloridalicense.com/dbpr/ddc/ddc_helpful_links.html (last visited Jan. 21, 2017).
[22] 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. *See* Rules 61N-1.017 and 61N-1.018(3)((g), F.A.C.

DBPR, but may be obtained from the FDA,[23] and other organizations, such as Enterprise Florida.[24]

III. Effect of Proposed Changes:

The requirement that Florida cosmetic manufacturers register cosmetic products with the division is eliminated. In addition, the bill makes conforming changes by eliminating registration and renewal requirements for cosmetic products, including the requirements to submit applications, product labels, and fees to the division. Florida cosmetic manufacturers' products will be treated in a similar manner to those cosmetic products manufactured outside of Florida that are distributed and sold in the state.[25]

The bill also removes the authorization to the DBPR to issue a "certificate of free sale" certifying that a cosmetic is registered with the DBPR and may be legally sold in Florida.[26]

The bill provides an effective date of July 1, 2017.

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:

SB 114 removes fees for cosmetic product registrations and renewals, as well as fees for the issuance of certificates of free sale for cosmetic products.

---

[23] *See* http://www.fda.gov/Cosmetics/InternationalActivities/Exporters/ucm129593.htm#Are_there_other (last visited Jan. 21, 2017).

[24] 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 Jan. 21, 2017). These online sites offer certificates of free sale services: http://icmad.org/programs/certificates-of-free-sale (last visited Jan.. 21, 2017), http://www.personalcarecouncil.org/member-industry-resources/certificates-free-sale (last visited Jan. 21, 2017), and http://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-request-form.pdf (last visited Jan. 21, 2017).

[25] *See 2017 Agency Legislative Bill Analysis (AGENCY: Department of Business and Professional Regulation)* for SB 114, dated January 11, 2017 and revised January 20, 2017 (on file with Senate Committee on Regulated Industries) at page 2.

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

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 DBPR for certificates of free sale, to obtain that service from third parties.

C. Government Sector Impact:

For Fiscal Year 2017-2018, the DBPR estimates that the bill will have a negative fiscal impact of $307,509 on the Professional Regulation Trust Fund within DBPR, and a $24,601 reduction in the service charge paid to the General Revenue Fund.[27]

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 $307,509[28] in Fiscal Year 2017-2018, $388,451 in Fiscal Year 2018-2019, and $494,248 in Fiscal Year 2019-2020. The deficit in the Drugs, Devices, and Cosmetics account within the Professional Regulation Trust Fund is anticipated to continue.

The bill contains an appropriation of $222,564 in recurring funds from the General Revenue Fund for Fiscal Year 2017-2018 for implementation of the bill. The appropriation from the Professional Regulation Trust Fund is reduced by the same amount.

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.

[27] *See 2017 Agency Legislative Bill Analysis (AGENCY: Department of Business and Professional Regulation)* for SB 114, dated January 11, 2017 and revised January 20, 2017 (on file with Senate Committee on Regulated Industries) at page 3.
[28] The total amount of estimated cosmetic products revenue to DBPR in Fiscal Year 2017-2018 of $307,509 is the sum of: $74,010 (new main product registrations), $27,150 (new identical product registrations), $164,280 (main product registration renewals), $39,900 (identical product registration renewal), and $2,169, (fees for issuance of certificates of free sale (COFS)). *See 2017 Agency Legislative Bill Analysis (AGENCY: Department of Business and Professional Regulation)* for SB 114, dated January 11, 2017 and revised January 20, 2017 (on file with Senate Committee on Regulated Industries) at page 5.

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.