HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 673 Cosmetic Product Registration
SPONSOR(S): Latvala
TIED BILLS: **IDEN./SIM. BILLS:** SB 612

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	Castagna	O'Callaghan
2) Government Operations Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) is responsible for regulating cosmetic products in the United States. The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety.

The Florida Department of Business and Professional Regulation's 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. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division.

HB 673 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. 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 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 has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[1] The federal Food and Drug Administration's (FDA) definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[2]

The FDA regulates cosmetics under the authority of the federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[3] A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[4] A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[5] The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[6]

Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products regulated such as drugs and medical devices with regard to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers but allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products. The FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[7]

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[8] Voluntary submission to the VCRP provides the FDA with information on cosmetic businesses and products, which helps support product safety review processes.[9] As of February 2015,

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[1] Landa, Michael. "Examining the Current State of Cosmetics," testimony on March 27, 2012, before the Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives, accessible at http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last viewed February 25, 2015).
[2] 21 C.F.R. §720.4(c)(12) (1992).
[3] Corby-Edwards, Amalia, Congressional Research Service, FDA Regulation of Cosmetics and Personal Care Products, July 9, 2012, accessible at http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last viewed February 23, 2015).
[4] *Id.*
[5] *Supra fn.* 3.
[6] Food and Drug Administration, *FDA Authority over Cosmetics*, March 20, 2014, accessible at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last viewed February 23, 2015).
[7] *Supra fn*. 3.
[8] Federal Food and Drug Administration, *Voluntary Cosmetic Registration Program*, accessible at http://www.fda.gov/Cosmetics/RegistrationProgram/UCM2005171.htm (last viewed February 23, 2015).
[9] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*

there are 2,446 active online accounts, 1,252 registered establishments, and 42,325 product formulations on file with the VCRP.[10]

The FDA does not require good manufacturing practices (GMP) for cosmetic products as it does with drugs and medical devices, unless the product is considered both a cosmetic and a drug.[11] GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards. With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.[12]

Labeling

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[13] FDA regulations require cosmetic product labels to disclose:[14]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[15] and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[16] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[17]

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

State's Cosmetic Laws

[10] Federal Food and Drug Administration, *Registration Reports*, accessible at http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last viewed February 26, 2015).
[11] In some cases products that are used for two purposes are considered both a cosmetic and a drug. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Such products must comply with the requirements for both cosmetics and drugs. Food and Drug Administration, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?),* http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last viewed February 25, 2015).
[12] *Supra fn*. 3.
[13] 15 U.S.C. 1451-1460 (2009).
[14] *Supra fn.* 1.
[15] Federal Food and Drug Administration, *Prohibited and Restricted Ingredients*, accessible at http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last viewed February 26, 2015).
[16] *Supra fn.* 1.
[17] *Supra fn.* 6.

All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.[18] Further cosmetic related laws and regulation vary state by state. Very few states, including Louisiana[19] and Florida, have mandatory registration requirements for both cosmetic products and manufacturers. New Jersey [20] and Pennsylvania [21] require only cosmetic facilities, not products, to be registered with their respective state agencies. Other states, such as Texas [22] and Illinois, [23] authorize their respective state agencies to issue certificates of free sale for the export of in-state produced products.

California and Washington require post-market product reporting. The California Safe Cosmetics Act requires cosmetic manufacturers to notify the state of any product ingredients that are on state or federal lists of chemicals that cause cancer or birth defects.[24] Washington only requires this notification for children's cosmetic products.[25]

Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) serves to protect the health, safety, and welfare of Florida citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics[26] by administering the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act).[27]

The Act conforms to FDA cosmetic laws and regulations and authorizes the Division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

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.[28] 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.[29]
Cosmetic manufacturers must complete and submit an application, pass an onsite inspection,[30] and pay a fee. The application fee is $800 for a biennial permit, including renewal requirements, and a one-

[18] Federal Food and Drug Administration, *Subchapter 3.3- State Operational Authority,* accessible at http://www.fda.gov/ICECI/Inspections/IOM/ucm122520.htm (last viewed on February 26, 2015).
[19] Louisiana Dep't of Health and Human Services, *Cosmetics*, accessible at http://dhh.louisiana.gov/index.cfm/page/727 (last viewed on February 26, 2015).
[20] New Jersey Dep't of Health, *Wholesale Food and Cosmetic Project,* accessible at http://www.nj.gov/health/foodanddrugsafety/wfcp.shtml (last viewed February 26, 2015).
[21] Pennsylvania Dep't of Health, *Drug, Device, and Cosmetic Program*, accessible at http://www.health.pa.gov/facilities/Laws%20and%20Regulations/DDCR/Pages/DDC_Main.aspx#.VO9dB2xOncs (last viewed February 26, 2015).
[22] 25 Tex. Admin. Code §§ 229.301-229.306 (2010).
[23] Ill. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).
[24] Campaign for Safe Cosmetics, *State Legislation,* accessible at http://www.safecosmetics.org/get-the-facts/regulations/legislation/ (last viewed February 26, 2015).
[25] *Id.*
[26] Florida law defines a cosmetic as an article, with the exception of soap, that is: (a) intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; or (b) intended for use as a component of any such article. Section 499.003(12), F.S.
[27] Florida Dep't of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics,* accessible at http://www.myfloridalicense.com/DBPR/ddc/index.html (last viewed February 23, 2015).
[28] Florida Dep't of Business and Professional Regulation, *Cosmetic Manufacturer,* accessible at http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last viewed February 25, 2015).
[29] Section 499.01(2)(o), F.S.
[30] If the applicant also holds a drug manufacturer permit at the same time an inspection is not required. *Supra fn*. 28.

time pre-permit inspection fee of $150.[31] Currently, there are 125 establishments with Division issued permits.[32]

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: [33]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

Registration of Products

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[34] Products that are both a cosmetic and a drug must be registered as a drug.[35] Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product. The application includes the following information: [36]

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Identification of cosmetic product, whether domestic or exported, from the following categories:
    - Baby products;
    - Bath preparations;
    - Eye makeup preparations;
    - Fragrance preparations;
    - Hair preparations (not color related);
    - Hair coloring preparations;
    - Makeup preparations (not eye area);
    - Manicuring preparations;
    - Oral hygiene preparations;
    - Personal cleanliness;
    - Shaving preparations;
    - Skin care preparations (creams, lotions, powder, and sprays); and
    - Suntan preparations.
- Name of product as shown on label;
- Identification of the product if it is for professional use only;
- Manufacturer of the product including their name, city, and state; and
- Signed affidavit section.

[31] *Supra fn.* 28.
[32] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with committee staff).
[33] Rule 61N-1.010, F.A.C.
[34] Section 499.015(1)(a), F.S.
[35] Rule 61N-1.016(1)(a), F.A.C.
[36] Florida Dep't of Business and Professional Regulation, Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228, accessible at http://www.myfloridalicense.com/DBPR/ddc/ProductRegistrationforCosmetics.html (last viewed February 26, 2015).

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.[37] 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 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.[38]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[39] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[40] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug.[41]

The majority of cosmetic product registration applicants are not voluntarily registered with the FDA and are in noncompliance with FDA warning and labeling requirements. Oftentimes to spare the applicant from an application denial, the Division assists the applicant in correcting their product labels to be in compliance and properly registered.[42] The cosmetic product renewal process does not include a product and label review as is required when the product is initially registered with the Division.[43]

Currently, there are 7,278 active cosmetic product registrations[44] and from 2013 to 2014, the Division approved 1,196 cosmetic product registrations.[45] The Division's average processing time for cosmetic product registration is approximately 60 days.[46]

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[47] The Division, when requested by a cosmetic manufacturer, issues a certificate of free sale for a registered cosmetic product that is to be exported to another country.[48]

Effect of Proposed Changes

HB 673 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. 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.

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[37] Rule 61N-1.016(4)(b), F.A.C.
[38] Rule 61N-1.016(1)(b), F.A.C.
[39] Rule 61N-1.009, F.A.C.
[40] Florida Dep't of Business and Professional Regulation, 2015 Legislative Bill Analysis HB 673 (on file with committee staff).
[41] *Supra fn.* 32.
[42] *Supra fn.* 32.
[43] *Supra fn.* 32.
[44] *Supra fn*. 40.
[45] *Supra fn*. 32.
[46] *Supra fn.* 32.
[47] Food and Drug Administration, *FDA Export Certificate,* December 18, 2014, accessible at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last viewed February 24, 2015).
[48] Rule 61N-1.017, F.A.C.

This 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 provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1. Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
Section 2. Amends s. 499.003, F.S., relating to definitions.
Section 3. Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registration, and free-sale certificates.
Section 4. Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division will experience a decrease in revenues associated with no longer receiving payment of fees for cosmetic product registration, product registration renewal, and certificates of free sale (COFS). There are 7,278 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 7,278 products are approximately $187,275.00 (or $93,637.50 annually). In Fiscal Year 2013-14, the Division received $52,470.00 in new product registration fees. In Fiscal Year 2013-14, the Division received $7,862.00 in COFS fees. [49]

If enacted, HB 673 will cause an estimated Fiscal Year 2015-16 revenue reduction of $176,115.50 [$93,637.50 (annual renewals) + $72,450.00 (initial product registrations) + $10,028.00 (COFS)]. This amount is estimated to increase annually.[50] The negative fiscal impact on the Division is significant.

The State General Revenue Fund will experience a decrease in revenues associated with the 8% surcharge on Division revenues collected. Approximately $14,089 will not be contributed to the State General Revenue Fund in fiscal year 2015-2016.[51]

2. Expenditures:

The Division will incur minimal costs associated with rulemaking which can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a positive fiscal impact for cosmetic manufacturers associated with no further payment of product registration and renewal fees to the Division.

D. FISCAL COMMENTS:

[49] *Supra fn.*40.
[50] *Supra fn*.40.
[51] *Supra fn*.40.

Revenue reductions will accelerate the timeline for the Drugs, Devices and Cosmetics Trust Fund (DDCTF) to be in a deficit. With these reductions, the DDCTF is anticipated to be in a deficit by Fiscal Year 2016-17.[52]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[52] *Supra fn*. 40.