

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 211 Cosmetic Product Registration  
**SPONSOR(S):** Health Quality Subcommittee; Latvala  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 114

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Royal	McElroy
2) Government Operations & Technology Appropriations Subcommittee	11 Y, 0 N	Topp	Topp
3) Health & Human Services Committee	18 Y, 0 N	Royal	Calamas

### SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) regulates 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 (DBPR) Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida must hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers must be registered with the Division. Florida is one of only three states that require cosmetic product registration.

The Division also provides certificates of free sale for cosmetic manufacturers to provide foreign customers regarding exported products. A certificate of free sale verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.

CS/HB 211 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill eliminates the fee to register cosmetics. 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. This allows cosmetic manufacturers in Florida to sell cosmetics without registering such products.

The bill removes the fee cap for cosmetic manufacturer permits and authorizes the Division to assess a fee sufficient to cover the costs of administering the cosmetic manufacturer program.

The bill removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S. Throughout the bill the term "Federal Drug Administration" is revised to correctly reference the federal Food and Drug Administration.

The bill will reduce fee revenue to the Division annually by approximately \$224,124. In addition, expenditures related to Cosmetic Product registration of \$138,873 will likely be realized as a potential cost savings. The bill has no fiscal impact on local governments. See *Fiscal Analysis and Economic Impact Statement*.

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

## 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.<sup>1</sup> 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.<sup>2</sup>

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 adulterating and misbranding cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.<sup>3</sup> A cosmetic is 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.<sup>4</sup> A cosmetic is 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.<sup>5</sup>

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.<sup>6</sup> However, 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.<sup>7</sup>

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.<sup>8</sup> FPLA regulations require cosmetic product labels to disclose:<sup>9</sup>

- 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.

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<sup>1</sup> 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. Available at:

<http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm> (last visited March 14, 2017).

<sup>2</sup> 21 C.F.R. §720.4(c)(12) (1992).

<sup>3</sup> Amalia Corby-Edwards, *FDA Regulation of Cosmetics and Personal Care Products*, CONGRESSIONAL RESEARCH SERVICE, July 9, 2012. Available at:

[http://asbcouncil.org/sites/default/files/library/docs/crs\\_report\\_fda\\_regulation\\_of\\_cosmetics\\_and\\_personal\\_care\\_products.pdf](http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf) (last visited March 14, 2017).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*. Available at:

<http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> (last visited March 14, 2017).

<sup>7</sup> *Supra*, note 3.

<sup>8</sup> 15 U.S.C. § 1451-1460 (2009).

<sup>9</sup> *Supra*, note 1.

## Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not require registration of cosmetic manufacturers or cosmetic products, but it allows cosmetic manufacturers to voluntarily register facilities, report product ingredients, and report adverse reactions to products.

Voluntary cosmetic registration 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.<sup>10</sup> Voluntary submission to the VCRP furnishes the FDA with information on cosmetic businesses and products, which helps support product safety review processes.<sup>11</sup> As of February 2017, there are 4,467 active online accounts, 2,058 registered cosmetic establishments, and 57,814 product formulations on file with the VCRP.<sup>12</sup>

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.<sup>13</sup> GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards.<sup>14</sup> 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.<sup>15</sup>

## Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufacturers 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, bithionol, methylene chloride, and mercury-containing compounds<sup>16</sup> and require warning statements on the labels of cosmetics that may be hazardous to consumers when misused.<sup>17</sup> 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.<sup>18</sup> 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:<sup>19</sup>

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<sup>10</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*. Available at: <http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm> (last visited March 14, 2017).

<sup>11</sup> 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.*

<sup>12</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*. Available at: <http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm> (last visited March 14, 2017).

<sup>13</sup> 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; however, 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 and must comply with the requirements for both cosmetics and drugs. U.S. FOOD AND DRUG ADMINISTRATION, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*. Available at: <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm> (last visited March 14, 2017).

<sup>14</sup> U.S. FOOD AND DRUG ADMINISTRATION. *Facts about the Current Good Manufacturing Practices*. Available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm> (last visited March 16, 2017).

<sup>15</sup> *Supra*, note 3.

<sup>16</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*. Available at: <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm> (last visited March 14, 2017).

<sup>17</sup> Examples of such products are: cosmetics in self-pressurized containers (aerosol products), feminine deodorant sprays, and children's bubble bath products. U.S. FOOD AND DRUG ADMINISTRATION, *Summary of Labeling Requirements*. Available at: [https://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126438.htm#Label\\_Warnings](https://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126438.htm#Label_Warnings) (last visited March 16, 2017).

<sup>18</sup> *Supra*, note 1.

<sup>19</sup> *Supra*, note 6.

- 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 Cosmetic Laws

All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.<sup>20</sup> Further cosmetic related laws and regulation vary state by state. Twenty-five states have enacted state food, drug and cosmetic laws similar to the federal FDCA that authorize inspections of cosmetic manufacturing facilities but do not provide any further legal authority over cosmetic manufacturers.<sup>21</sup> Eighteen states do not have a state food, drug, and cosmetic act, but federal law still authorizes these states to perform inspections of cosmetic manufacturing facilities.<sup>22</sup>

Only Louisiana, Nevada, and Florida, have mandatory registration requirements for both cosmetic manufacturers and individual cosmetic products.<sup>23</sup>

Seven states require only cosmetic manufacturer registration and California has a voluntary cosmetic manufacturer registration program.<sup>24</sup> Oregon and Washington require ingredient reporting.<sup>25</sup> California 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.<sup>26</sup> Washington also requires this type notification for children's cosmetic products.<sup>27</sup> Other states, such as Texas and Illinois,<sup>28</sup> authorize the issuance of certificates of free sale for the export of in-state produced cosmetic products.

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<sup>20</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Subchapter 3.3- State Operational Authority*. Available at: <https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123506.pdf> (last visited March 14, 2017).

<sup>21</sup> Office of Program Policy Analysis and Government Accountability (OPPAGA), *Cosmetic Regulation in Florida Research Memorandum*, February 21, 2017. (On file with the Health Quality Subcommittee staff).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

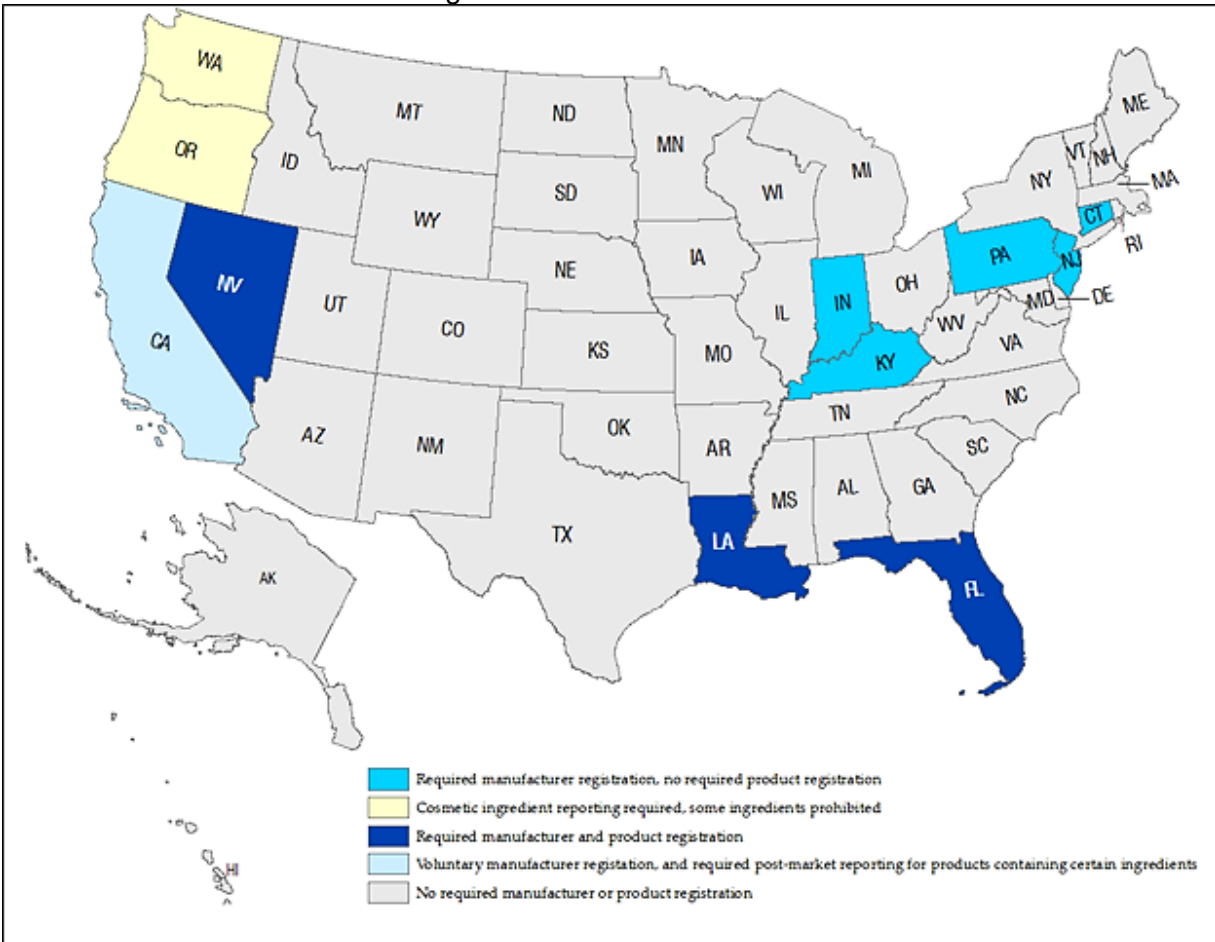
<sup>25</sup> *Id.*

<sup>26</sup> CALIFORNIA DEP'T OF PUBLIC HEALTH, *California Safe Cosmetic Program*. Available at: <http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx> (last visited March 16, 2017).

<sup>27</sup> WASH. REV. CODE §70.240.040 (2008)

<sup>28</sup> 25 Tex. Admin. Code §§ 229.301-229.306 (2010); Ill. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).

## State Laws and Regulations of Cosmetic Manufacturers and Products<sup>29</sup>



Source: Office of Program Policy Analysis and Government Accountability (OPPAGA)

### Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) administers the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act), which regulates cosmetic manufacturers to prevent adulteration, contamination, and misbranding of cosmetic products.<sup>30</sup> The Act conforms to FDA cosmetic laws and regulations and also 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.<sup>31</sup> Manufacture in this context means the preparing, deriving, compounding, propagating, processing, producing, or fabricating of any cosmetic.<sup>32</sup> 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.<sup>33</sup> A person that only labels or changes the

<sup>29</sup> *Supra*, note 21.

<sup>30</sup> FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics*. Available at: <http://www.myfloridalicense.com/DBPR/ddc/index.html> (last visited March 15, 2017).

<sup>31</sup> S. 499.01(2)(o), F.S.

<sup>32</sup> FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Cosmetic Manufacturer*. Available at: <http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html> (last visited March 16, 2017).

<sup>33</sup> *Id.*

label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.<sup>34</sup>

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection,<sup>35</sup> and pay a fee. Applicants must pay a fee of \$800 for a biennial permit and a one-time pre-permit inspection fee of \$150.<sup>36</sup> Currently, there are 129 establishments with cosmetic manufacturer permits.<sup>37</sup>

To ensure cosmetic product safety and quality and compliance with FDA laws and regulations, the Division requires cosmetic manufacturers to meet certain minimum requirements, which include:<sup>38</sup>

- 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 must 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 must be maintained in a clean and sanitary condition;
- Components, containers, and closures must not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems must provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- Procedures to facilitate a rapid and effective recall or market withdrawal.

#### *Product Registration*

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.<sup>39</sup> Products that are both a cosmetic and a drug must be registered as a drug.<sup>40</sup> To register a cosmetic product, a manufacturer must submit a detailed application, a copy of the product labels, and a \$30 fee for each product.<sup>41</sup> The application includes the following information:

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label;
- Identification of the product, if it is for professional use only;
- Manufacturer of the product, including its name, city, and state;
- Identical cosmetic products information; and
- Signed affidavit attesting that all information in the application is true and correct.<sup>42</sup>

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.<sup>43</sup> Each product registration must be renewed every two years, including a \$30 renewal fee.

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<sup>34</sup> Id.

<sup>35</sup> If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. *Supra*, note 32.

<sup>36</sup> *Supra*, note 32.

<sup>37</sup> *Supra*, note 21.

<sup>38</sup> Rule 61N-1.010, F.A.C.

<sup>39</sup> S. 499.015(1)(a), F.S.

<sup>40</sup> Rule 61N-1.016(1)(a), F.A.C.

<sup>41</sup> S. 499.015, F.S.

<sup>42</sup> FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228*. Available at [http://www.myfloridalicense.com/DBPR/ddc/documents/Product\\_Registration\\_Cosmetic\\_App-228.pdf](http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf) (last visited March 16, 2017).

<sup>43</sup> Rule 61N-1.016(4)(b), F.A.C.

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 and is therefore, an “identical product”. The registration 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.<sup>44</sup> The Division has not taken any enforcement actions against cosmetic manufacturers within the past year for the failure to register a cosmetic.

The Division reviews applicants’ product labels to determine compliance with the requirements of the FDCA.<sup>45</sup> 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.<sup>46</sup> 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.<sup>47</sup> At the end of the fiscal year 2015-2016, there were 13,024 active cosmetic product registrations with the Division.<sup>48</sup>

### *Inspection and Investigation of Cosmetic Manufacturers*

Passing an onsite inspection is a prerequisite to the issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.<sup>49</sup> Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to announced or unannounced inspection and investigation by the Division and the Department of Law Enforcement.<sup>50</sup> Inspections and investigations may include:

- Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any cosmetic;
- Entry to any establishment, vehicle or space therein in which cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;
- Entry to any establishment, vehicle, or space therein in which records related to cosmetics are held;
- Surveillance of procedures related to cosmetics;
- Collection of facts and information related to cosmetics;
- Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to cosmetics;
- Sampling any cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;
- Photographing any cosmetic including any related component, materials, physical plant, storage condition, article or product;
- Observations and identification of:
  - Any cosmetic consisting wholly or in part of filthy, putrid or decomposed substances;
  - Any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a cosmetic becoming adulterated or misbranded;
  - Any unsanitary conditions or practices which may render a cosmetic injurious to health;
  - Any faulty manufacturing, processing, packaging, or holding of cosmetics as related to current GMP including recordkeeping;
  - Any deviation from recommended processing, storage or temperature requirements for any cosmetic as specified by federal or state law;

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<sup>44</sup> Rule 61N-1.016(1)(b), F.A.C.

<sup>45</sup> FLORIDA DEP’T OF BUSINESS AND PROFESSIONAL REGULATION, 2017 Legislative Bill Analysis SB 114, March 9, 2017. (On file with Health Quality Subcommittee staff).

<sup>46</sup> *Id.*

<sup>47</sup> 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 Health Quality Subcommittee staff).

<sup>48</sup> *Supra*, note 45.

<sup>49</sup> *Supra*, note 32.

<sup>50</sup> S. 499.051(1), F.S.; Rule 61N-1.019(1)-(3), F.A.C.

- Any deviation from FDA requirements for the label and labeling of any cosmetic;
- Any other action to determine compliance with chapters 499 and 893<sup>51</sup>, F.S., and chapter 61N-1, F.A.C.
- Taking of evidence related to a cosmetic that is or may be in violation of chapters 499 or 893, F.S., or any rules adopted thereunder; and
- Securing the removal of any potentially misbranded or adulterated cosmetic from commerce or public access.

### *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.<sup>52</sup> A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.<sup>53</sup> A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.<sup>54</sup>

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.<sup>55</sup> Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a \$30.00 fee.<sup>56</sup> Although not required by law, the FDA will also issue a COFS for a cosmetic product upon request.<sup>57</sup>

### **Effect of Proposed Changes**

CS/HB 211 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. Florida cosmetic manufacturers' products would be treated the same as cosmetic products manufactured outside of Florida but distributed and sold into Florida. 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.

Florida cosmetic manufacturers would continue to be regulated. They would still be required to have their facilities permitted and be subject to inspection and investigation of their cosmetic products.

The bill removes the fee cap for cosmetic manufacturer permits and authorizes the Division to assess a fee sufficient to cover the costs of administering the cosmetic manufacturer program. This allows the Division to offset the projected minor deficit for Fiscal Year 2017-2018 for the cosmetic program and eliminates the need for the Division to seek General Revenue funds or a fee cap increase from the Legislature every time the cosmetic program is expected to have a deficit.

The bill also removes the Division's authority to issue COFSs for registered cosmetic products in s. 499.003(6), F.S. While COFSs would not be available from the Division for exported cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

<sup>51</sup> Ch. 893, F.S. is The Florida Comprehensive Drug Abuse and Prevention Act.

<sup>52</sup> U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate*. Available at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>, (last visited March 17, 2017).

<sup>53</sup> *Id.*

<sup>54</sup> Enterprise Florida, *Certificate of Free Sale*. Available at <https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf> (last visited March 15, 2017).

<sup>55</sup> Rule 61N-1.017, F.A.C.

<sup>56</sup> *Supra*, note 54.

<sup>57</sup> *Supra*, note 52.



Throughout the bill the term “federal Drug Administration” is revised to correctly reference the federal Food and Drug Administration.

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

**B. SECTION DIRECTORY:**

**Section 1:** Amends 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.

**Section 2:** Amends 499.003, F.S., relating to definitions.

**Section 3:** Amends 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free sale certificates.

**Section 4:** Amends 499.051, F.S., relating to inspections and investigations.

**Section 5:** Creates an unnumbered section relating appropriation of funds.

**Section 6:** Provides an effective date of July 1, 2017.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

**1. Revenues:**

The DBPR estimates that during Fiscal Year 2017-2018, the Division would have the following revenues and expenditures for cosmetic manufacturer permits and cosmetic product registrations.<sup>58</sup>

Permit	Revenue	Expenditures	Surplus
Cosmetic Manufacturer	\$70,998	\$43,557	\$27,441
Cosmetic Product Registration	\$224,124	\$138,873	\$85,251

The bill will eliminate fees currently paid by cosmetic manufacturers for cosmetic product registration and renewal totaling \$224,124 annually.

The DBPR should anticipate a reduction in workload related to the elimination of cosmetic production registration and a potential savings of \$138,873 in expenditures.

The estimated loss of Service Charge to General Revenue is anticipated to be \$17,929 annually.

The loss of revenue attributed to COFS is likely to be \$2,778 annually based on revenues received in FY 2015-16.<sup>59</sup>

The bill removes the fee cap for cosmetic manufacturer permits and authorizes the Division to assess a fee sufficient to cover the costs of administering the cosmetic manufacturer program.

**2. Expenditures:**

See Revenues.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

**1. Revenues:**

None.

<sup>58</sup> Florida Department of Business and Professional Regulation, Allocation of Revenues and Expenditures FY 2017-18, on file with the Government Operations and Technology Subcommittee, March 23, 2017.

<sup>59</sup> Florida Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, Allocation of Revenues and Expenditures Fiscal Year Ending in 2016 (On File with the Health Quality Committee).

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 the \$30 per product registration fee, \$15 per identical product registration fee, and \$30 and \$15 biennial renewal fees to the Division.

The bill may have a negative fiscal impact on cosmetic manufacturers if the Division needs to raise the cosmetic manufacturer permit fee to offset a deficit that may be caused by repealing the cosmetic product registration requirement. However, the Division projects that cosmetic manufacturer permit program will experience a surplus rather than a deficit for FY 2017-2018. Therefore, a fee increase is unlikely to be necessary.

D. FISCAL COMMENTS:

DBPR has not identified what activities are included in the expenditures for product registration. It is possible that DBPR is counting manufacturer inspection activities in the product registration category, which are more appropriately attributed as expenditures under the manufacturer permit. If so, such inspections would need to continue, and the reduction in workload may be less than the \$138,873 estimated here. If workload is reduced by a smaller amount, the cosmetic program may experience a deficit. Any deficit could be eliminated by DBPR increasing the manufacturer permit fee, as authorized by the bill.

However, it is unlikely that a manufacturer permit fee increase would be necessary, even in the event of a deficit. In FY 2016-2017 the Legislature appropriated \$740,000 in General Revenue (\$640,000 recurring and \$100,000 nonrecurring) to the Division to cover revenue deficits anticipated in (non-cosmetic) license programs.<sup>60</sup> To date, the Division has not used any these funds. In the event the Division chooses not to raise cosmetic manufacturer fees, the Division could use that those GR appropriations to cover any deficit in FY 2017-2018 and in future years. No other appropriation is necessary to implement the bill.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The 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.

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<sup>60</sup> Fiscal Year 2016-2017 General Appropriation Act, Ch. 2016-66 L.O.F., Line 2010.

#### **IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On March 21, 2017, the Health Quality Subcommittee adopted an amendment that:

- Removed the fee cap for cosmetic manufacturer permits and authorizes the Division to assess a cosmetic manufacturer permit fee that is sufficient to cover the costs of administering the cosmetic program.
- Removed the recurring appropriation of General Revenue funds to the Division for Fiscal Year 2017-2018.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.