

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 113 Florida Drug and Cosmetic Act

SPONSOR(S): Roach

TIED BILLS: **IDEN./SIM. BILLS:** SB 172

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	8 Y, 5 N	Morris	McElroy
2) Local, Federal & Veterans Affairs Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The U.S. Food and Drug Administration (FDA) regulates all over-the-counter (OTC) drug products marketed in the U.S., including sunscreen, to ensure that their benefits outweigh their risks, that they can be used safely in an unsupervised setting, and that they are properly labeled. 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.

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act (FLDCA), requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. The DBPR's Division of Drugs, Devices and Cosmetics (DDC) oversees the activities of companies manufacturing and/or distributing products within Florida. The DDC inspects, monitors and investigates persons and establishments subject to the FLDCA, including applicants for permits and permitted establishments, for compliance with the FLDCA and agency rules. The DDC investigates violations of the FLDCA and state and federal statutes, rules, regulations related to drugs, devices and cosmetics.

The Florida Constitution grants local governments broad home rule authority. Specifically, municipalities have governmental, corporate, and proprietary powers that enable them to conduct municipal government, perform their functions and provide services, and exercise any power for municipal purposes, except as otherwise provided by law. Where state preemption applies, it precludes a local government from exercising authority in that particular area.

Florida law does not currently preempt the regulation of OTCs or cosmetics to the state. Thus, local governments may pass ordinances regulating OTCs and cosmetics as long as such ordinances do not conflict with state and federal law.

HB 113 amends s. 499.002 to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state.

The bill has no fiscal impact on state and local governments.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Over-the-Counter Drugs and Cosmetics – Federal Regulation

Over-the Counter Drug Regulation

The U.S. Food and Drug Administration (FDA) defines over-the counter (OTC) drug products as nonprescription drugs that are safe and effective for use by the general public without seeking treatment by a health professional.¹ The FDA regulates all OTC drug products marketed in the U.S. to ensure that their benefits outweigh their risks, that they can be used safely in an unsupervised setting, and that they are properly labeled.²

The FDA reviews the active ingredients and the labeling of classes of drugs instead of individual drug products. Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellent, nasal decongestant, and sunscreen. For each class, an OTC drug monograph³ is developed and published in the Federal Register.⁴ OTC drug monographs are active ingredient-based general regulations including acceptable ingredients, dosage forms, labeling, and required testing for each OTC drug class.⁵

Sunscreen Regulation

In the U.S., sunscreen ingredients are treated like over-the-counter drugs and are carefully regulated. Currently, the FDA has approved 16 acceptable active ingredients in products that are labeled as sunscreen.⁶ Active ingredients are those ingredients protecting skin from the sun's ultraviolet rays.⁷ Inactive ingredients are all other ingredients which are not active.⁸

On February 26, 2019, the FDA published a proposed rule, Sunscreen Products for Over-the-Counter Human Use.⁹ The proposed rule classifies the safety and effectiveness of certain active ingredients and dosage forms, updates sunscreen testing and recordkeeping requirements, and addresses new uses of sunscreens, including the sale of combination sunscreen-insect repellent products. The FDA proposed a 90-day comment period, and comments must be submitted on or before May 28, 2019.¹⁰

¹ U.S. Food and Drug Administration, *Drug Applications for Over-the-Counter (OTC) Drugs*, available at: <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> (last visited Oct. 25, 2019)

² U.S. Food and Drug Administration, *Office of Drug Evaluation IV: What We Do*, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-drug-evaluation-iv-what-we-do> (last visited Oct. 30, 2019).

³ An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are "generally recognized as safe and effective" (GRASE) and not misbranded.

⁴ *Supra*, note 1.

⁵ *Supra*, note 2.

⁶ U.S. Food and Drug Administration, *Sunscreen: How to Help protect Your Skin from the Sun*, <https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun> (last visited Oct. 30, 2019).

⁷ *Id.*

⁸ *Id.*

⁹ Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use*, <https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use> (last visited Oct. 30, 2019).

¹⁰ *Id.*

There are currently 16 active ingredients allowed in sunscreen. Out of these current ingredients, the FDA is proposing to change the status of the following ingredients:¹¹

- Zinc oxide and titanium dioxide are proposed to be categorized as generally recognized as safe and effective;
- Para-aminobenzoic acid and trolamine salicylate are proposed to be categorized as no longer generally recognized as safe; and
- The remaining 12 ingredients are proposed to be identified as not having enough information to determine whether they are safe and effective and the FDA has asked the industry for additional data.

Cosmetic Regulation

The FDA regulates cosmetics¹² 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.¹³ 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.¹⁴ 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.¹⁵

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.¹⁶ 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.¹⁷

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.¹⁸ FPLA regulations require cosmetic product labels to disclose:¹⁹

- 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.

Voluntary Regulations

¹¹ U.S. Food and Drug Administration, *FDA advances new proposed regulation to make sure sunscreens are safe and effective*, <https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective> (last visited Oct. 30, 2019).

¹² The FDA's 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. 21 C.F.R. §720.4(c)(12) (1992).

¹³ 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 (last visited Nov. 1, 2019).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*. Available at: <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> (last visited Nov. 1, 2019).

¹⁷ *Id.*

¹⁸ 15 U.S.C. § 1451-1460 (2009).

¹⁹ *Id.*

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.²⁰ Voluntary submission to the VCRP furnishes the FDA with information on cosmetic businesses and products, which helps support product safety review processes.²¹ 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.²²

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.²³ GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards.²⁴ 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.²⁵

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 compounds²⁶ and require warning statements on the labels of cosmetics that may be hazardous to consumers when misused.²⁷ 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.²⁸ 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:²⁹

²⁰ U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*. Available at: <http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm> (last visited Nov. 1, 2019).

²¹ 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.*

²² U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*. Available at: <http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm> (last visited Nov. 1, 2019).

²³ 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 Nov. 1, 2019).

²⁴ 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 Nov. 1, 2019).

²⁵ *Supra*, note 23.

²⁶ U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*. Available at: <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm> (last visited Nov. 1, 2019).

²⁷ 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 (last visited Nov. 1, 2019).

²⁸ *Supra*, note 26.

²⁹ *Supra*, note 26.

- 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.

OTC Drugs and Cosmetics – Florida Regulation

The Department of Business and Professional Regulation (DBPR) is the agency charged with licensing and regulating businesses and professionals in the State of Florida, including those in the drugs, devices and cosmetics industries. DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.³⁰

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act (FLDCA), requires DBPR to regulate drugs, devices, and cosmetics.³¹ Most of the FLDCA's regulations relate to the distribution of prescription drugs. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits.

DBPR's Division of Drugs, Devices and Cosmetics (DDC) oversees the activities of companies manufacturing and/or distributing products within the State of Florida. The DDC inspects, monitors and investigates persons and establishments subject to the FLDCA, including applicants for permits and permitted establishments, for compliance with the FLDCA and agency rules. The DDC investigates violations of the FLDCA, the rules, and state and federal statutes, rules, regulations and other laws concerning drugs, devices and cosmetics. It also serves as a statewide subject matter expert for the FLDCA and agency rules and reviews product registrations.

Sunscreen Regulation

Scientific studies have indicated that there is a decline in the health of coral reefs. Coral reefs around the world have been stressed to the point of turning white, or "bleaching," which happens when they expel the energy-supplying algae that live within them.³² Recent studies have found that sunscreen chemicals in many popular products actually hurt corals. According to one report, "The main chemical culprits are oxybenzone and octinoxate, ... once these chemicals are in the water, they actually decrease corals' defenses against bleaching This damage, along with harm from other stressors including ocean acidification, water pollution, rising sea temperatures, and coral disease, prevents corals from successfully reproducing and surviving in current marine environments."³³

Scientists disagree, however, on whether the evidence merits banning sales of certain types of sunscreens.³⁴ The Office of Program Policy Analysis and Government Accountability (OPPAGA) recently compiled peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life. OPPAGA stated in the overview of its findings that:³⁵

³⁰ Ss. 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

³¹ S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.

³² Downs, C.A., Kramarsky-Winter, E., Segal, R. et al., *Arch Environ Contam Toxicol* (2016, <https://doi.org/10.1007/s00244-015-0227-7> (last visited Oct. 25, 2019).

³³ The Ocean Conservancy, *Is Your Sunscreen Killing the Coral Reef?*, <https://oceanconservancy.org/blog/2018/05/24/sunscreen-killing-coral-reef/> (last visited Oct. 25, 2019).

³⁴ Rebecca Beitsch, *Sunscreen bans aimed at protecting coral reefs spark debate — among scientists*, *The Washington Post* (Mar. 2018), https://www.washingtonpost.com/national/health-science/sunscreen-bans-aimed-at-protecting-coral-reefs-spark-debate--among-scientists/2019/03/15/b35d4030-4512-11e9-8aab-95b8d80a1e4f_story.html?noredirect=on&utm_term=.142b4cf4fee6 (last visited Oct. 25, 2019).

³⁵ Office of Program Policy Analysis and Government Accountability, *Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) (on file with Health and Human Services Committee staff).

A small number of scientific studies have shown negative effects³⁶ of oxybenzone and octinoxate on corals and marine life at concentration levels generally not observed in nature. Sunscreens are not the only source of these chemicals; they may also be introduced to seawater from wastewater effluent, leaching from plastics, and leaching from hull paints on ships. Setting aside the effects of these chemicals, a number of stressors would continue to affect corals, including natural threats such as hurricanes and increases in average ocean temperatures, air pollution, and land-based pollution.

In response to these studies, Hawaii became the first state to ban certain types of sunscreens. The July 2018 law prohibits the sale, offer of sale, and distribution of sunscreens that contain the chemicals oxybenzone and octinoxate beginning January 1, 2021.³⁷ Florida does not regulate sunscreen on a statewide basis however, the Key West City Commission passed a local ordinance banning certain types of sunscreens. Beginning in January 2021, the sale of sunscreens containing oxybenzone and octinoxate will be prohibited within the city limits of Key West.³⁸

Local Government Authority

The Florida Constitution grants local governments broad home rule authority. Specifically, non-charter county governments may exercise those powers of self-government that are provided by general or special law.³⁹ Those counties operating under a county charter have all powers of self-government not inconsistent with general law or special law approved by vote of the electors.⁴⁰

Likewise, municipalities⁴¹ have those governmental, corporate, and proprietary powers that enable them to conduct municipal government, perform their functions and provide services, and exercise any power for municipal purposes, except as otherwise provided by law.⁴²

Preemption

Local governments have broad authority to legislate on any matter that is not inconsistent with federal or state law. A local government enactment may be inconsistent with state law if (1) the Legislature "has preempted a particular subject area" or (2) the local enactment conflicts with a state statute. Where state preemption applies, it precludes a local government from exercising authority in that particular area.⁴³

Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.⁴⁴ Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.⁴⁵ In cases where the Legislature expressly or specifically preempts an area, the intent of the Legislature is readily ascertained.⁴⁶ In cases determining the validity of ordinances enacted in the face of state preemption, the effect has been to find such ordinances null and void.⁴⁷

³⁶ Identified negative effects that may be occurring include bleaching of coral fragments and coral cells from hard coral and damage to coral DNA and reduced reproductive success.

³⁷ HAW. REV. STAT. § 342D (2019).

³⁸ Lindsey Bever, *We have one reef: Key West bans popular sunscreens to help keep coral alive*, The Washington Post, (Feb. 6, 2019), https://www.washingtonpost.com/climate-environment/2019/02/06/we-have-one-reef-key-west-bans-popular-sunscreens-help-keep-coral-alive/?utm_term=.a4f0e5cd60da (last visited Oct. 25, 2019).

³⁹ Art. VIII, s. 1(f), Fla. Const.

⁴⁰ Art. VIII, s. 1(g), Fla. Const.

⁴¹ A municipality is a local government entity created to perform functions and provide services for the particular benefit of the population within the municipality, in addition to those provided by the county. The term "municipality" may be used interchangeably with the terms "town," "city," and "village."

⁴² Art. VIII, s. 2(b), Fla. Const. See also s. 166.021(1), F.S.

⁴³ Wolf, *The Effectiveness of Home Rule: A Preemption and Conflict Analysis*, 83 Fla. B.J. 92 (June 2009), available at <https://www.floridabar.org/the-florida-bar-journal/the-effectiveness-of-home-rule-a-preemption-and-conflict-analysis/> (last visited Oct. 25, 2019).

⁴⁴ See *City of Hollywood v. Mulligan*, 934 So. 2d 1238, 1243 (Fla. 2006); *Phantom of Clearwater, Inc. v. Pinellas County*, 894 So. 2d 1011, 1018 (Fla. 2d DCA 2005), approved in *Phantom of Brevard, Inc. v. Brevard County*, 3 So. 3d 309 (Fla. 2008).

⁴⁵ *Mulligan*, 934 So. 2d at 1243.

⁴⁶ *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So. 3d 880, 886 (Fla. 2010).

⁴⁷ See, e.g., *Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami*, 812 So.2d 504 (Fla. 3d DCA 2002).

Proposed Changes

HB 113 amends s. 499.002 to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state. This includes the local regulation of sunscreen products.

B. SECTION DIRECTORY:

- Section 1** Amends s. 499.002, relating to purpose, administration, and enforcement of and exemption from part I of chapter 499.
- Section 2** Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES