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 Commerce and Tourism

BILL:	SB 1718
INTRODUCER:	Senator Book
SUBJECT:	Cosmetic Animal Testing
DATE:	January 21, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Renner	McKay	CM	**Pre-meeting**
2.			AP	
3.			RC	

I. Summary:

SB 1718 creates the Humane Cosmetics Act and prohibits a manufacturer from manufacturing, importing for profit, selling, or offering for sale a cosmetic developed or manufactured using cosmetic animal testing conducted or contracted by the manufacturer or any supplier of the manufacturer, with certain exceptions.

A violation of this act constitutes a civil penalty of $5,000 and an additional $1,000 for each day a person continues to violate the act. Violations may be enforced by the Attorney General, state attorney, or the city attorney or county attorney of the city or county in which the violation occurred.

The bill does not appear to have a fiscal impact on state or local government.

The bill takes effect July 1, 2022.

II. Present Situation:

Licensing and Regulation of Drugs, Devices and Cosmetics in Florida

The Florida Drug and Cosmetic Act (act) is found in part I of ch. 499, F.S.[1] The act's purpose is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[2] The Department of Business and Professional Regulation (DBPR) is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[3]

[1] Section 499.001, F.S., provides that ss. 499.001-499.94 is the Florida Drug and Cosmetic Act.
[2] Section 499.002(1)(a), F.S.
[3] Section 499.002(2), F.S.

Administration of the act must conform to the Federal Food, Drug, and Cosmetic Act[4] and the applicable portions of the Federal Trade Commission Act,[5] which prohibit the false advertising of drugs, devices, and cosmetics.[6]

DBPR's Division of Drugs, Devices and Cosmetics (division) issues permits to over-the-counter drug manufacturers and cosmetic manufacturers and inspects permittees and enforces the act.[7]

In addition to the above, the act also provides:[8]

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulations for the advertising and labeling of drugs, devices, and cosmetics; and
- Enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

Over-the-Counter Drugs and Cosmetics

Part I of Ch. 499, F.S., Definitions

A "proprietary drug," or "OTC drug," is defined as a patent or over-the-counter drug in its unbroken, original package, which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded, and can be purchased without a prescription.[9] The term "cosmetic" is defined as an article, with the exception of soap, that is: a) intended to be rubbed, poured, sprinkled, or sprayed on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance; or (b) intended for use as a component of any such article.[10]

U.S. Food and Drug Administration Role and Guidance

Florida's drugs, devices and cosmetics regulations must conform to the Federal Food, Drug, and Cosmetic Act.[11] The U.S. Food and Drug Administration (FDA) defines "over-the counter drug products" as nonprescription drugs that are safe and effective for use by the general public without seeking treatment by a health professional.[12] The FDA reviews the active ingredients and the labeling of classes of drugs instead of individual drug products because there are over 300,000 marketed OTC drug products.[13] For each class, an OTC drug monograph[14] is developed and published in the Federal Register. According to the FDA, OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.[15]

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[4] 21 U.S.C. ss. 301 *et seq*.
[5] *See* 15 U.S.C. §§ 41-58, as amended.
[6] Section 499.002(1)(b), F.S.
[7] *Id*.
[8] *See* ss. 499.0051, 499.0054, and 499.062, F.S.
[9] Section 499.003(43), F.S.
[10] Section 499.003(12), F.S.
[11] *See supra* note 5.
[12] 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 Jan. 21, 2022).
[13] *Id*.
[14] 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.
[15] *See supra* note 5.

The FDA defines "cosmetic products" in a fashion similar to the definition of cosmetic in s. 499.003(12), F.S.[16] Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants. Cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives.[17]

FDA Guidance on Animal Testing and Cosmetics

The FDA advises cosmetic manufacturers to employ whatever testing is appropriate and effective for substantiating the safety of their products. However, "in all cases where animal testing is used, FDA advocates that research and testing derive the maximum amount of useful scientific information from the minimum number of animals and employ the most humane methods available within the limits of scientific capability."[18] The FDA also believes that consideration should be given "to the use of scientific alternative methods to whole-animal testing."[19]

III. Effect of Proposed Changes:

The bill creates the Humane Cosmetics Act and prohibits a manufacturer[20] from:

- Manufacturing, importing for profit, selling, or offering for sale a cosmetic developed or manufactured using cosmetic animal testing conducted or contracted by the manufacturer or any supplier[21] of the manufacturer.
- Conducting or contracting for cosmetic animal testing.

The bill defines "cosmetic animal testing" as the internal or external application of a cosmetic in its final form or any ingredient used in the formulation of such cosmetic to the skin, eyes, or other body part of a live, nonhuman vertebrate. Reviewing, assessing, or retaining evidence from a cosmetic animal test does not constitute developing or manufacturing a cosmetic using animal testing.

The prohibitions do not apply if cosmetic animal testing is conducted to comply with the following:

- A requirement of a federal or state law or regulation, if all of the following apply:
  - The ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function.

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[16] *See* U.S. Food and Drug Administration, *FDA Authority over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated, available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_kinds (last visited Jan. 21, 2022)

[17] *Id.*

[18] *See* U.S. Food and Drug Administration, *Animal Testing & Cosmetics* (8/24/2020), *available at* https://www.fda.gov/cosmetics/product-testing-cosmetics/animal-testing-cosmetics (last visited Jan. 21, 2022).

[19] *Id.*

[20] The bill defines a "manufacturer" as any person whose name appears on the label of a cosmetic pursuant to requirements of the name and place of business of the manufacturers, packers, or distributors on cosmetic labels under 21 C.F.R. § 701.12, as those requirements exist on July 1, 2022.

[21] The bill defines a "supplier" as the entity that supplies, directly or through a third party, any ingredient used in the formulation of a manufacturer's cosmetics.

  - A specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.
  - There is no non-animal alternative method accepted for the relevant endpoint by the relevant federal or state authority.
- Chapter V of the Federal Food, Drug, and Cosmetic Act relating to drugs and devices;
- A requirement of a foreign regulatory authority if no evidence derived from such testing was relied upon to substantiate the safety of the cosmetic sold in the state by the manufacturer; or
- For noncosmetic purposes, a requirement of a federal, state, or foreign regulatory authority if no evidence derived from such testing was relied upon to substantiate the safety of the cosmetic sold in the state by the manufacturer.

For the above exceptions, manufacturers must include a statement printed on the label or packaging of the cosmetic stating: "This product or an ingredient used in the formulation of this product has been tested on animals."

A person who violates the Humane Cosmetics Act is subject to a civil penalty of $5,000 and an additional $1,000 for each day a person continues to violate the act. Violations may be enforced by the Attorney General, state attorney, or the city attorney or county attorney of the city or county in which the violation occurred. The civil penalty must be remitted to the entity authorized to bring an action to enforce such penalty.

The bill takes effect July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Manufacturers are prohibited from importing for profit, selling, or offering for sale a cosmetic developed or manufactured using cosmetic animal testing, with certain exceptions, and is subject to a $5,000 civil penalty for violating the Humane Cosmetics Act and an additional $1,000 for each day a person continues to violate the act.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The language in the bill does not limit the prohibitions to activity in Florida.

VIII. Statutes Affected:

This bill creates section 499.075 of the Florida Statutes.

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.