A bill to be entitled

An act relating to the testing of cosmetics on animals; providing a short title; amending s. 499.005, F.S.; providing that it is unlawful for a person to manufacture, repackage, sell, hold, or offer for sale cosmetics that have been tested on animals as part of the manufacturing process; creating s. 499.0095, F.S.; prohibiting manufacturers from using animal testing as part of the cosmetics manufacturing process; prohibiting manufacturers from repackaging, selling, holding, or offering for sale cosmetics that have been tested on animals; providing exceptions; providing that manufacturers, upon issuance of a cosmetic manufacturer permit, consent to specified inspections by the Department of Business and Professional Regulation; providing a penalty for refusal to allow such inspections; requiring holders of such permits to submit to the department certain written documentation by a specified date each year; providing for criminal penalties; providing an administrative penalty; providing for a cause of action by the department; authorizing the department to adopt rules; amending ss. 499.01, 499.003, and 499.0051, F.S.; conforming a provision and cross-references to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Sickles High School Ought to be a Law Cosmetic Animal Testing Act of 2026."

Section 2. Present subsections (5) through (29) of section 499.005, Florida Statutes, are redesignated as subsections (6) through (30), respectively, and a new subsection (5) is added to that section, to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(5) The manufacture, repackaging, sale, holding, or offering for sale of cosmetics that have been tested on animals as part of the manufacturing process.

Section 3. Section 499.0095, Florida Statutes, is created to read:

499.0095 Cosmetics tested on animals prohibited.—

(1)(a) A manufacturer may not use animal testing as part of the process to manufacture cosmetics.

(b) A manufacturer may not repackage, sell, hold, or offer for sale cosmetics that have been tested on animals.

(2) This section does not apply to the manufacturing of cosmetics, or the repackaging, selling, holding, or offering for sale of cosmetics, if animal testing of such products is:

(a) Required by federal law.

(b) Conducted to comply with the requirements of a foreign regulatory authority or the laws of any foreign country.

(c) Conducted for purposes other than cosmetic purposes, and the data collected from such testing is not used to evaluate the safety or effectiveness of cosmetics sold in this state.

(3)(a) A manufacturer, upon issuance of a cosmetic manufacturer permit pursuant to s. 499.01(2)(p), consents to the department's authorized officer or employee entering and inspecting the premises on an annual basis to determine compliance with this section and department rules, as applicable. A refusal to allow an authorized officer or employee of the department to enter the premises or to conduct an inspection is a violation of s. 499.005(7) and is grounds for disciplinary action pursuant to s. 499.066.

(b) By January 31 of each year, each holder of a cosmetic manufacturer permit issued pursuant to s. 499.01 shall submit to the department written documentation to verify his or her compliance with this section.

(4)(a) A person who violates this section or s. 499.005 commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(b) In addition to the criminal penalties imposed in paragraph (a), a person who violates this section is subject to an administrative penalty of $5,000 for each violation. Each day

the violation continues constitutes a separate violation. Penalties collected pursuant to this paragraph are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this section.

(c) In addition to other penalties, the department may institute such suits or other legal proceedings as are required to enforce this section pursuant to s. 499.066.

(5) The department may adopt rules to implement this section.

Section 4. Paragraph (p) of subsection (2) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(p) *Cosmetic manufacturer permit.*—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph. A person who manufactures cosmetics and has annual gross sales of $25,000 or less is exempt from the permit requirements of this paragraph, unless such person manufacturers cosmetics using animal testing as part of the manufacturing process. Upon request, an exempt cosmetic manufacturer must provide to the department written documentation to verify his or her annual gross sales, including

all sales of cosmetic products at any location, regardless of the types of products sold or the number of persons involved in the operation.

1. An exempt cosmetic manufacturer may only:

a. Sell prepackaged cosmetics affixed with a label containing information required by the United States Food and Drug Administration.

b. Manufacture and sell cosmetics that are soaps, not otherwise exempt from the definition of cosmetics, lotions, moisturizers, and creams.

c. Sell cosmetics that are not adulterated or misbranded in accordance with 21 U.S.C. ss. 361 and 362.

d. Sell cosmetic products that are stored on the premises of the cosmetic manufacturing operation.

2. Each unit of cosmetics manufactured under this paragraph must contain, in contrasting color and not less than 10-point type, the following statement: "Made by a manufacturer exempt from Florida's cosmetic manufacturing permit requirements."

3. The department may investigate any complaint which alleges that an exempt cosmetic manufacturer has violated an applicable provision of this chapter or a rule adopted under this chapter. The department's authorized officer or employee may enter and inspect the premises of an exempt cosmetic manufacturer to determine compliance with this chapter and

department rules, as applicable. A refusal to permit an authorized officer or employee of the department to enter the premises or to conduct an inspection is a violation of s. 499.005(7) ~~s. 499.005(6)~~ and is grounds for disciplinary action pursuant to s. 499.066.

4. This paragraph does not exempt any person from any state or federal tax law, rule, regulation, or certificate or from any county or municipal law or ordinance that applies to cosmetic manufacturing.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6). The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from

whom they purchase active pharmaceutical ingredients under this section. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(15) ~~s. 499.005(14)~~, and a knowing failure is a violation of s. 499.0051(3).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the

department to administer this subsection, is a violation of s. 499.005(15) ~~s. 499.005(14)~~, and a knowing failure is a violation of s. 499.0051(3).

Section 5. Paragraphs (a) and (b) of subsection (48) of section 499.003, Florida Statutes, are amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(22) ~~s. 499.005(21)~~ if such activity is conducted in accordance with s. 499.01(2)(h):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The distribution of a prescription drug or an offer to distribute a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution of a prescription drug among hospitals

or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The distribution of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the distribution of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must

maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(22) ~~s. 499.005(21)~~ if such activity is

conducted in accordance with rules established by the department:

1. The distribution of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution of a prescription drug or offer to distribute a prescription drug for emergency medical reasons, which may include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person

licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

6. The distribution of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes prescription drugs pursuant to this subparagraph must reconcile all drugs distributed and returned and resolve any discrepancies in a timely manner.

Section 6. Paragraph (a) of subsection (10) of section 499.0051, Florida Statutes, is amended to read:

499.0051 Criminal acts.—

(10) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—

(a) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after

a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates s. 499.005(9) or (11) ~~s. 499.005(8) or (10)~~ with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

Section 7. This act shall take effect January 1, 2027.