By the Committee on Rules; the Appropriations Committee on Agriculture, Environment, and General Government; the Committee on Regulated Industries; and Senators Gruters and Calatayud

595-03665-25 2025196c3

A bill to be entitled

An act relating to chemicals in consumer products; amending s. 499.003, F.S.; revising the definition of the term "drug"; defining the term "vaccine or vaccine material"; amending s. 499.007, F.S.; deeming a drug misbranded if it is a food containing a vaccine or vaccine material, but its label does not include specified information; creating s. 499.0095, F.S.; defining terms; requiring that, beginning on a specified date, cosmetics manufactured, sold, offered or distributed for sale, or distributed for use in this state provide notice of specified added ingredients on the single-use packaging of such cosmetics; prohibiting, by a specified date, cosmetics that release formaldehyde from being manufactured, sold, offered or distributed for sale, or distributed for use in this state, unless it is a natural byproduct with no functional or technical purpose; providing an exception; providing construction; providing penalties and remedies; providing applicability; authorizing the Department of Business and Professional Regulation to adopt rules; amending s. 500.03, F.S.; defining the term "messenger ribonucleic acid vaccine" or "mRNA vaccine"; amending s. 500.04, F.S.; prohibiting the use of fruits and vegetables to deliver an mRNA vaccine; amending s. 500.11, F.S.; deeming a food misbranded if it contains a vaccine or vaccine material, but its label does not include specified information; amending ss. 499.01 and

499.05, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Present subsections (47), (48), and (49) of section 499.003, Florida Statutes, are redesignated as subsections (48), (49), and (50), respectively, a new subsection (47) is added to that section, and subsections (17) and (40) of that section are amended, to read:

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

(17) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; ~~or~~

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories; or

(e) Food as defined in s. 500.03 which contains a vaccine or vaccine material.

(40) "Prescription drug" means a prescription, medicinal,

or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003, s. 499.007(13), subsection (31), or subsection (48) ~~(47)~~, except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(47) "Vaccine or vaccine material" means a substance authorized or approved by the United States Food and Drug Administration which is intended for use in humans to stimulate the production of antibodies and provide immunity against disease and which is prepared from the causative agent of a disease, its products, or a synthetic substitute and is treated to act as an antigen without inducing the disease.

Section 2. Present subsection (17) of section 499.007, Florida Statutes, is redesignated as subsection (18), and a new subsection (17) is added to that section, to read:

499.007 Misbranded drug or device.—A drug or device is misbranded:

(17) If it is a food as defined in s. 500.03 and contains a vaccine or vaccine material, but its label does not bear, in type of uniform size and prominence, the words "contains vaccine or vaccine material" and does not specify that the food is classified as a drug under the Florida Drug and Cosmetic Act.

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

499.0095 Presence of certain ingredients in cosmetics; notice required.—

(1) As used in this section, the term:

(a) "Incidental ingredient" means a substance that has no technical or functional effect in the cosmetics but is present by reason of having been incorporated into the cosmetics as an ingredient of another cosmetic ingredient.

(b) "Ingredient" means:

1. Any chemical or mixture of chemicals intentionally used in the manufacturing of cosmetics. The term does not include any incidental ingredient that is present in cosmetics at insignificant levels or that has no technical or functional effect; or

2. A processing aid, including any of the following:

a. A substance that is used in the processing of cosmetics but is removed from the cosmetics in accordance with good manufacturing practices before the cosmetics are packaged in their finished form.

b. A substance that is used in the processing of cosmetics for its technical or functional effect to produce the cosmetics and is then converted to a substance the same as constituents of a declared ingredient, in accordance with good manufacturing practices, and does not significantly increase the concentration of such constituents before the cosmetics are packaged in their finished form.

c. A substance that is used in the processing of cosmetics for its technical or functional effect to produce the cosmetics in accordance with good manufacturing practices, that is present in the cosmetics' finished form at insignificant concentrations, and that does not have any technical or functional effect in such cosmetics.

(c) "Ortho-phthalates" means esters of ortho-phthalic acid.

(d) "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.

(2) Except as provided in subsection (5), beginning July 1, 2026, cosmetics manufactured, sold, offered or distributed for sale, or distributed for use in this state must provide notice on such cosmetics' single-use packaging of the following intentionally added chemicals or chemical classes:

(a) Ortho-phthalates.

(b) PFAS.

(c) Formaldehyde as identified in CAS 50-00-0.

(d) Methylene glycol as identified in CAS 463-57-0.

(e) Mercury as identified in CAS 7439-97-6.

(f) Triclosan as identified in CAS 3380-34-5.

(g) M-phenylenediamine or its salt derivatives as identified in CAS 108-45-2.

(h) O-phenylenediamine or its salt derivatives as identified in CAS 95-54-5.

(3) Except as provided in subsection (5), beginning July 1, 2026, cosmetics manufactured, sold, offered or distributed for sale, or distributed for use in this state must provide notice on such cosmetics' single-use packaging of any lead or lead compounds as identified by CAS 7439-92-1, whether intentionally added or naturally occurring, at 10 parts per million or more, or as otherwise determined by department rule.

(4) Except as provided in subsection (5), beginning July 1, 2026, cosmetics manufactured, sold, offered or distributed for sale, or distributed for use in this state may not release

formaldehyde as identified in paragraph (2)(c) unless it is a natural byproduct with no functional or technical purpose.

(5) A retailer in possession of cosmetics that do not comply with the requirements of this section as of July 1, 2026, may exhaust its existing stock through sales to the public until July 1, 2027.

(6) A violation of this section is subject to the penalties and remedies provided in s. 499.066.

(7) This section does not apply to cosmetic products regulated as drugs by the United States Food and Drug Administration.

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

Section 4. Present paragraphs (t) through (z) of subsection (1) of section 500.03, Florida Statutes, are redesignated as paragraphs (u) through (aa), respectively, and a new paragraph (t) is added to that subsection, to read:

500.03 Definitions; construction; applicability.—

(1) For the purpose of this chapter, the term:

(t) "Messenger ribonucleic acid vaccine" or "mRNA vaccine" means a vaccine that uses laboratory-produced messenger ribonucleic acid to trigger the human body's immune system to generate an immune response.

Section 5. Subsection (12) is added to section 500.04, Florida Statutes, to read:

500.04 Prohibited acts.—The following acts and the causing thereof within the state are prohibited:

(12) The use of a fruit or vegetable as a delivery mechanism for an mRNA vaccine as defined in s. 500.03.

Section 6. Paragraph (q) is added to subsection (1) of section 500.11, Florida Statutes, to read:

500.11 Food deemed misbranded.—

(1) A food is deemed to be misbranded:

(q) If it contains a vaccine or vaccine material as defined in s. 499.003, unless its label bears, in type of uniform size and prominence, the words "contains vaccine or vaccine material" and specifies that the food is classified as a drug under the Florida Drug and Cosmetic Act.

Section 7. Paragraphs (a), (b), and (h) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in distribution of prescription drugs for which the person is the manufacturer and must comply with s. 499.0121 and all other provisions of this part and rules adopted under this part. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(49)(j) ~~s. 499.003(48)(j)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) *Prescription drug repackager permit.*—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

3. A prescription drug repackager permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control which each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(49)(a)3. ~~s. 499.003(48)(a)3.~~

(h) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(49)(a) ~~s. 499.003(48)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(49)(j) ~~s. 499.003(48)(j)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of

the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician, as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control that each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(49)(a)3. ~~s. 499.003(48)(a)3.~~

Section 8. Paragraphs (i) and (l) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(49)(b)2. ~~s. 499.003(48)(b)2.~~ or s. 499.82.

(l) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(49)(a)-(v) ~~s. 499.003(48)(a)-(v)~~ or s. 499.82(14).

Section 9. This act shall take effect July 1, 2025.