By Senator Gruters

22-00130-25 2025196__

A bill to be entitled

An act relating to foods containing vaccines or vaccine materials; 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; 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. 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 4. 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 5. 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 6. This act shall take effect July 1, 2025.