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## STATE OF RHODE ISLAND

### IN GENERAL ASSEMBLY

#### **JANUARY SESSION, A.D. 2014**

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### AN ACT

### RELATING TO FOOD & DRUGS - RHODE ISLAND FOOD DRUGS & COSMETICS ACT

Introduced By: Representatives Canario, Azzinaro, Guthrie, Johnston, and Edwards

Date Introduced: January 09, 2014

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Sections 21-31-2 and 21-31-15 of the General Laws in Chapter 21-31 entitled "Rhode Island Food, Drugs, and Cosmetics Act" are hereby amended to read as follows:

#### **21-31-2. Definitions. --** For the purpose of this chapter:

(1) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(2) "Color additive" means a material which: (i) Is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source; and (ii) When added or applied to a food, drug or cosmetic, or to the human body or any of its parts, is capable, alone or through reaction with other substance, of imparting color thereto, except that the term "color additive" does not include any material exempted by regulation under the federal act, or which the commissioner, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring; (iii) The term "color" includes black, white and intermediate grays, as well as all other colors; (iv) Nothing in subdivision (2) of this section shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical used, or intended to be used, solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil which thereby affects its color, whether before or after harvest.

1	(2)(3) "Contaminated with filth" applies to any food, drug, device, or cosmetic not
2	securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from
3	all foreign or injurious contaminations.
4	(3)(4) "Cosmetics" means: (i) articles intended to be rubbed, poured, sprinkled, or
5	sprayed on, introduced into, or applied to the humanbody human body or any part of the body its
6	parts for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (ii)
7	articles intended for use as a component of any articles described in this subdivision, except that
8	this term shall not include soap.
9	(5) "Cultivated commercially" means grown or raised by a person or entity in the course
10	of business or trade and sold within the state.
11	(4)(6) "Device" (except when used in subdivision (23) (40) of this section and in sections
12	21-31-3(10), 21-31-11(6), 21-31-15(a)(3), and 21-31-18(3)) means instruments, apparatus, and
13	contrivances, including their components, parts, and accessories, intended: (i) for use in the
14	diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or (ii)
15	to affect the structure or any function of the body of humans or other animals.
16	(5)(7) "Director" means the director of health.
17	(6)(8) "Distressed merchandise" means any food which has had the label lost or which
18	has been subjected to possible damage due to accident, fire, flood, adverse weather, or to any
19	other similar cause, and which may have been rendered unsafe or unsuitable for human or animal
20	consumption or use.
21	(9) "Distributor" means a person or entity that sells, supplies, furnishes or transports food
22	in this state that such person or entity does not produce.
23	(7)(10) "Dosage form" means the form of the completed drug product (such as tablet,
24	syrup, or suppository).
25	(8)(11) "Drug" means: (i) articles recognized in the official United States
26	Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National
27	Formulary, or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure,
28	mitigation, treatment, or prevention of disease in humans or other animals; (iii) articles (other
29	than food) intended to affect the structure or any function of the body of humans or other animals;
30	and (iv) articles intended for use as a component of any article specified in paragraphs (i), (ii) or
31	(iii) of this subdivision; but does not include devices or their components, parts, or accessories.
32	(9)(12) "Drug product" means a dosage form containing one or more active therapeutic
33	ingredients along with other substances included during the manufacturing process.
34	(13) "Enzyme" means a protein that catalyzes chemical reactions of other substances

2 (10) (i) (14)(i) "Equivalent and interchangeable" means having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or 3 4 National Formulary, or their successors, if applicable, and not found in violation of the 5 requirements of the United States Food and Drug Administration, or its successor agency, or the 6 department of health. 7 (ii) "Generic" means the chemical or established name of a drug or drug product. 8 (11) (15) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 9 section 301 et seq. (12) (16) "Food" means: (i) articles used for food or drink for humans or other animals, 10 11 (ii) chewing gum, and (iii) articles used for components of any article described in this 12 subdivision. 13 (17) "Food additive" means any substance the intended use of which results or 14 reasonably may be expected to result, directly or indirectly, in its becoming a component or 15 otherwise affecting the characteristics of any food, including any substance intended for use in 16 producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use, if such substance 17 18 is not generally recognized, among experts qualified by scientific training and experience to 19 evaluate its safety, as having been adequately shown through scientific procedures or, in the case 20 of a substance used in food prior to January 1, 1958, through either scientific procedures or 21 experience based on common use in food, to be safe under the conditions of its intended use; 22 except that such term does not include: (i) A pesticide chemical in or on a raw agricultural 23 commodity; or (ii) A pesticide chemical to the extent that it is intended for use or is used in the 24 production, storage or transportation of any raw agricultural commodity; or (iii) A color additive; 25 or (iv) any substance used in accordance with a sanction or approval granted prior to June 12, 26 1963, or the federal food, drug, and cosmetic act, the poultry products inspection act (21 U.S.C. § 27 451 et seq.) or the meat inspection act of March 4, 1907, as amended. 28 (18) "Genetically engineered" or "genetic engineering" means a process whereby any 29 food intended for human consumption: (i) Is produced from an organism or organisms in which 30 the genetics are materially altered through the application of: (A) In vitro nucleic acid techniques, 31 including recombinant DNA (deoxyribonucleic acid) techniques, the direct injection of nucleic 32 acid into cells or organelles, encapsulation, gene deletion and doubling; or (B) Methods of fusing cells that do not fall within the same taxonomic family, that overcome natural physiological 33 34 reproductive or recombinant barriers and that are not techniques used in traditional breeding and

without being destroyed or altered upon completion of such reactions.

1	selection such as conjugation, transduction and hybridization; (ii) Is treated with a material
2	described in subparagraph (A) of this subdivision, except manure that is used as a fertilizer for a
3	raw agricultural commodity; or (iii) Contains an ingredient, component or substance described in
4	subparagraph (i) of this subdivision.
5	(13) (19) (i) "Label" means a display of written, printed, or graphic matter upon the
6	immediate container of any article; and a requirement made by or under authority of this chapter
7	that any word, statement, or other information appearing on the label shall not be considered to be
8	complied with unless the word, statement, or other information also appears on the outside
9	container or wrapper, if any, of the retail package of the article, or is easily legible through the
10	outside container or wrapper.
11	(ii) "Immediate container" does not include package liners.
12	(iii) "Labeling" means all labels and other written, printed, or graphic matter: (A) upon
13	an article or any of its containers or wrappers, or (B) accompanying the article.
14	(iv) If an article is alleged to be misbranded because the labeling is misleading, or if an
15	advertisement is alleged to be false because it is misleading, then in determining whether the
16	labeling or advertisement is misleading there shall be taken into account (among other things) not
17	only representations made or suggested by statement, word, design, device, sound, or in any
18	combination of them, but also the extent to which the labeling or advertisement fails to reveal
19	facts material in the light of the representations or material with respect to consequences which
20	may result from the use of the article to which the labeling or advertisement relates under the
21	conditions of use prescribed in the labeling or advertisement or under the conditions of use that
22	are customary or usual.
23	(20) "Manufacturer" means a person who produces seed, stock or food and sells such
24	item to a retailer or distributor.
25	(14) (21) "Native" means a product harvested in Rhode Island and is limited to the
26	following:
27	(i) "Bay scallop" means Argopecten irradians.
28	(ii) "Bay quahog" means Mercenaria mercenaria.
29	(iii) "Steamer clams" means Mya arenaria.
30	(iv) "Mussels" means Mytilus edulis.
31	(v) "Oysters" means Crassostrea virginica.
32	(22) "Natural food" means food: (i) Which has not been treated with preservatives,
33	antibiotics, synthetic additives, artificial flavoring or artificial coloring; (ii) Which has not been
34	processed in a manner that makes such food significantly less nutritive; and (iii) Which has not

1	been genetically engineered, as defined in § 21-31-2(18). Processing of food by extracting,
2	purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not, of itself,
3	prevent the designation of such food as "natural food".
4	(15) (23) "New drug" means: (i) any drug the composition of which is such that the drug
5	is not generally recognized among experts qualified by scientific training and experience to
6	evaluate the safety of drugs as safe for use under conditions prescribed, recommended, or
7	suggested in the labeling of it; or (ii) any drug the composition of which is such that the drug, as a
8	result of investigations to determine its safety for use under those conditions has become so
9	recognized, but which has not, otherwise than in the investigations, been used to a material extent
10	or for a material time under those conditions.
11	(16) (24) "Official compendium" means the official United States Pharmacopoeia,
12	official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any
13	supplement to any of them.
14	(25) "Organically grown" means produced through organic farming methods, which
15	involve a system of ecological soil management and mechanical or biological methods to control
16	insects, weeds, pathogens and other pests and which rely on crop rotation, crop residues,
17	composted animal manures, legumes, green manures, composted organic waste or mineral-
18	bearing rocks and not genetically engineered, as defined in § 21-31-2(18).
19	(26) "Organism" means any biological entity capable of replication, reproduction or
20	transferring genetic material.
21	(17) (27) "Patient" means, as the case may be: (i) the individual medically requiring a
22	drug, for whom a drug is prescribed; or (ii) the owner or the agent of the owner of an animal
23	medically requiring a drug, for which a drug is prescribed.
24	(18) (28) "Person" includes individual, partnership, corporation, and association.
25	(29) "Pesticide chemical" means any substance which, alone, in chemical combination or
26	in formulation with one or more other substances is an "economic poison" within the meaning of
27	the federal insecticide, fungicide and rodenticide act, 7 U.S.C. §§ 135-135k, and which is used in
28	the production, storage or transportation of raw agricultural commodities.
29	(19) (30) "Pharmacist" means a person duly registered with the board of pharmacy as a
30	compounder, dispenser, or supplier of drugs upon prescription, including registered assistant
31	pharmacists as defined by law.
32	(20) (31) "Pharmacy" means a place where drugs, medicines, or poisons are sold at retail
33	or where prescriptions of physicians, dentists, veterinarians, and other practitioners authorized to
34	issue prescriptions for drugs, medicines, and poisons are compounded, dispensed, supplied or

1 sold.
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(21) (32) "Practitioner" means a person authorized by law to practice medicine, dentistry,
 osteopathy, chiropody, or veterinary medicine in this state.

(22) (33) "Prescription" means an order, issued in good faith in the course of professional practice only, by a practitioner to a pharmacist for a drug for a particular patient, which specifies the date of its issue, the name and address of the practitioner, the name and address of the patient (and, if the drug is prescribed for an animal, the species of the animal), the name and quantity of the drug prescribed, directions for the use of the drug, and the signature of the practitioner; provided, that a prescription received by word of mouth, telephone, or other means of communication shall be reduced promptly to writing by the pharmacist in the form prescribed in this subdivision, and the record so made shall constitute the original prescription to be filed and preserved by the pharmacist; and, provided, further, that any refill authorization received by word of mouth, telephone, or other means of communication shall be reduced promptly to writing by the pharmacist, with the date of it on the face or on the reverse side of the original prescription.

(34) "Processed food" means any food other than a raw agricultural commodity and includes any food produced from a raw agricultural commodity that has been processed through canning, smoking, pressing, cooking, freezing, dehydration, fermentation or milling.

processing of such food but that is removed in some manner from the food before the food is packaged in a finished form; (ii) Any substance that is added to a food during processing, that is converted into constituents normally present in the food, and that does not significantly increase the amount of the constituents naturally found in the food; or (iii) Any substance that is added to a food for its technical or functional effect in the processing but that is present in the finished food at insignificant levels and that does not have any technical or functional effect in the finished food.

(36) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.

(37) "Retailer" means a person or entity that engages in the sale of food to a consumer.

(38) "Sale" means any and every sale and includes: (i) Manufacture, processing, packing, canning, bottling or any other production, preparation or putting up; (ii) Exposure, offer or any other proffer; (iii) Holding, storing or any other possessing; (iv) Dispensing, giving, delivering, serving or any other supplying; and (v) Applying, administering or any other using.

(23) (39) The representation of a drug, in its labeling or advertisement, as an antiseptic
shall be considered to be a representation that it is a germicide, except in the case of a drug
purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment,
dusting powder, or any other use that involves prolonged contact with the body.

(24) (40) The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any article for sale, and the sale, dispensing, and giving of any article, and the supplying or applying of the articles in the conduct of any food, drug, or cosmetic establishment.

<u>21-31-15. Misbranded drug or device. --</u> (a) A drug or device shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any way.

- (2) If in package form unless it bears a label containing: (i) the name and place of business of the manufacturer, packer, or distributor; and (ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under paragraph (ii) of this subdivision reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the director of health.
- (3) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed on it with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (4) If it is for use by humans and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of any of those substances, which derivative has been by the director of health after investigation found to be, and by regulations under this chapter designated as, habit forming, unless its label bears the name and quantity of the proportion of the substance or derivative and in juxtaposition with it the statement "Warning -- May be habit forming."
- (5) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears: (i) the common or usual name of the drug, if there is one; and (ii) in case it is fabricated from two (2) or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether,

chloroform, acetanilid, acetphenetidin, amidopyrine, anti-pyrine, atropine, hysoeine, hyoscyamine, arsenic, digitalis, glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of those substances contained in it; provided, that to the extent that compliance with the requirements of paragraph (ii) of this subdivision is impracticable, exemptions shall be established by regulations promulgated by the director of health.

- (6) Unless its labeling bears: (i) adequate directions for use; and (ii) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in the manner and form that are necessary for the protection of users; provided, that where any requirement of paragraph (i) of this subdivision, as applied to any drug or device, is not necessary for the protection of the public health, the director of health shall promulgate regulations exempting the drug or device from those requirements.
- (7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed in the compendium; provided, that the method of packing may be modified with the consent of the director of health. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.
- (8) If it has been found by the director of health to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of the precautions, that the director of health shall by regulations require as necessary for the protection of public health. No regulation shall be established for any drug recognized in an official compendium until the director of health shall have informed the appropriate body charged with the revision of the compendium of the need for packaging or labeling requirements and that body shall have failed within a reasonable time to prescribe those requirements.
- (9) If: (i) it is a drug and its container is made, formed, or filled as to be misleading; (ii) it is an imitation of another drug; or (iii) it is offered for sale under the name of another drug.
- 30 (10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.
  - (11) (i) A drug intended for use by humans which: (A) is a habit forming drug to which subdivision (a)(4) of this section applies; (B) because of its toxicity or the potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use

except under the supervision of a practitioner licensed by law to administer that drug; or (C) is limited by an effective application under section 21-31-16 to use under the professional supervision of a practitioner licensed by law to administer that drug shall be dispensed only: (I) upon a written prescription of a practitioner licensed by law to administer the drug, (II) upon an oral prescription of the practitioner which is reduced promptly to writing and filed by the pharmacist, or (III) by refilling any written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this subdivision shall be deemed to be an act that results in the drug being misbranded while held for sale.

- (ii) The director of health may by regulation remove drugs subject to subdivision (a)(4) of this section and section 21-31-16 from the requirements of paragraph (i) of this subdivision when those requirements are not necessary for the protection of the public health.
- (iii) A drug which is subject to paragraph (i) of this subdivision shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription." A drug to which paragraph (i) of this subdivision does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.
- (iv) No prescription for any of the drugs described in this subdivision shall be refilled if marked "non-repeat" or "N.R."
- (12) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 23-24.1-3 or 23-24.1-4 of the Poison Prevention Packaging Act.
- (13) If it is genetically engineered, as defined in § 21-31-2, and does not bear labeling as required in accordance with § 21-31-25 unless: (i) It is a food produced without the producer's knowledge that a seed or other component of the food was genetically engineered; or (ii) It is a processed food, as defined in § 21-31-2, that are genetically engineered, as defined in § 21-31-25, provided such genetically engineered materials do not, in the aggregate, account for more than nine-tenths of one per cent (.09%) of the total weight of the processed food.
- (b) (1) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe the drug, and any drug dispensed to an ultimate user by a practitioner, shall be exempt from the requirements of this section except subdivisions (a)(1), (9), and (11) of this section, and the packaging requirements of subdivisions (a)(7), (8), and (12) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in

1	the prescription, the name of the patient, and the directions for use and cautionary statements, if
2	any, contained in the prescription. When a practitioner prescribes a drug by brand name, oral,
3	written or electronic, he or she shall, in each prescription, authorize a less expensive generic
4	equivalent drug product by signing the prescription. Pursuant to section 42-127.1-7 and chapter
5	(19.1 of title 5) an electronic signature shall satisfy this requirement. If in the professional
6	judgment of the prescribing practitioner the brand name is medically necessary, the practitioner
7	shall indicate "Brand name necessary" on the prescription. This exemption shall not apply to any
8	drug dispensed in violation of paragraph (a)(11)(i) of this section.
9	(2) When dispensing a generic drug product, the word "INTERCHANGE" or the letters
10	"IC" must appear on the label followed by the generic name and manufacturer, and/or distributor,
11	of the chosen product.
12	(3) The requirements of subdivision (2) of this subsection only apply to single entity,
13	multiple-source drugs.
14	(4) When dispensing a single entity, single source drug, the trade name of the prescribed
15	drug will also appear on the label, and the generic name of the prescribed drug may also appear
16	on the label.
17	(5) When dispensing a fixed combination product, the United States Pharmacopoeia's
18	publication of Pharmacy Equivalent Names (PEN Names) for fixed combination products is the
19	official list of abbreviations for that labeling, and will be the approved abbreviation for
20	identifying the combination product dispensed. If no PEN name has been officially issued by the

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(6) Subdivisions (2) -- (5) of this subsection apply in all cases of dispensing by practitioners or pharmacists.

USP, the practitioner or pharmacist will label the medication secundum artem.

- (7) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may subsequently be included within the classifications stated in chapters 28 and 30 of this title.
  - SECTION 2. Chapter 21-31 of the General Laws entitled "Rhode Island Food, Drugs, and Cosmetics Act" is hereby amended by adding thereto the following section:
- 21-31-25. Labeling of genetically engineered products. (a) Any food, seed or seed stock offered or intended for retail sale in this state that is, or may have been, entirely or partially genetically engineered, except a processed food in which one or more processing aids or enzymes were produced or derived from genetic engineering, shall be labeled as follows: (1) In the case of food for retail sale contained in a package, by the manufacturer, distributor or retailer of the food, with the clear and conspicuous words: "Produced with Genetic Engineering"; (2) In the case of

1	food that is a raw agricultural commodity, on the package offered for retail sale or, in the case of
2	any such commodity that is not separately packaged or labeled, on the retail store shelf or bin that
3	holds such commodity displayed for sale, by the retailer, with the clear and conspicuous words
4	"Produced with Genetic Engineering"; and (3) In the case of any seed or seed stock, on the
5	container holding the seed or seed stock displayed for sale, the sales receipt, or any label
6	identifying ownership or possession of the commodity, by the manufacturer or distributor, with
7	the clear and conspicuous words: "Produced with Genetic Engineering".
8	(b) Notwithstanding any provision of law to the contrary contained in any general or
9	public law, rule or regulation, the director of health may adopt regulations, pursuant to chapter 31
10	of the general statutes, to implement and enforce the provisions of this section.
11	SECTION 3. This act shall take effect upon passage except the amendments to § 21-31-
12	15, and the new § 21-31-25, which shall take effect on January 1, 2015.

LC003103

## **EXPLANATION**

## BY THE LEGISLATIVE COUNCIL

OF

# AN ACT

## RELATING TO FOOD & DRUGS - RHODE ISLAND FOOD DRUGS & COSMETICS ACT

\*\*\*

This act would update and refine the definition section in the statutes on food, drugs, and cosmetics, most notable a new definition for genetically engineered products. It would also set forth rules for labeling such products.

This act would take effect upon passage except the amendments to § 21-31-15, and the new § 21-31-25, which would take effect on January 1, 2015.

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