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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

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A N A C T

RELATING TO FOOD AND DRUGS - RHODE ISLAND FOOD, DRUGS, AND COSMETICS
ACT

Introduced By: Representatives Tobon, Kazarian, Barros, Abney, and Diaz

Date Introduced: March 10, 2016

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

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

3 **21-31-2. Definitions.** -- For the purpose of this chapter:

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

7 (2) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely
8 protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all
9 foreign or injurious contaminations.

10 (3) "Cosmetics" means: (i) articles intended to be rubbed, poured, sprinkled, or sprayed
11 on, introduced into, or applied to the ~~humanbody~~ human body or any part of the body for
12 cleansing, beautifying, promoting attractiveness, or altering the appearance, and (ii) articles
13 intended for use as a component of any articles described in this ~~subdivision~~ chapter, except that
14 this term shall not include soap.

15 (4) "Device" (except when used in subdivision (23) of this section and in §§ 21-31-3(10),
16 21-31-11(6), 21-31-15(a)(3), and 21-31-18(3)) means instruments, apparatus, and contrivances,
17 including their components, parts, and accessories, intended: (i) for use in the diagnosis, cure,
18 mitigation, treatment, or prevention of disease in humans or other animals; or (ii) to affect the

1 structure or any function of the body of humans or other animals.

2 (5) "Director" means the director of health.

3 (6) "Distressed merchandise" means any food which has had the label lost or which has
4 been subjected to possible damage due to accident, fire, flood, adverse weather, or to any other
5 similar cause, and which may have been rendered unsafe or unsuitable for human or animal
6 consumption or use.

7 (7) "Dosage form" means the form of the completed drug product (such as tablet, syrup,
8 or suppository).

9 (8) "Drug" means: (i) articles recognized in the official United States Pharmacopoeia,
10 official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any
11 supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation,
12 treatment, or prevention of disease in humans or other animals; (iii) articles (other than food)
13 intended to affect the structure or any function of the body of humans or other animals; and (iv)
14 articles intended for use as a component of any article specified in paragraphs (i), (ii) or (iii) of
15 this subdivision; but does not include devices or their components, parts, or accessories.

16 (9) "Drug product" means a dosage form containing one or more active therapeutic
17 ingredients along with other substances included during the manufacturing process.

18 (10) (i) "Equivalent and interchangeable" means having the same generic name, dosage
19 form, and labeled potency, meeting standards of the United States Pharmacopoeia or National
20 Formulary, or their successors, if applicable, and not found in violation of the requirements of the
21 United States Food and Drug Administration, or its successor agency, or the department of health.

22 (ii) "Generic" means the chemical or established name of a drug or drug product.

23 (11) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et
24 seq.

25 (12) "Food" means: (i) articles used for food or drink for humans or other animals, (ii)
26 chewing gum, and (iii) articles used for components of any article described in this subdivision.

27 (13) (i) "Label" means a display of written, printed, or graphic matter upon the
28 immediate container of any article; and a requirement made by or under authority of this chapter
29 that any word, statement, or other information appearing on the label shall not be considered to be
30 complied with unless the word, statement, or other information also appears on the outside
31 container or wrapper, if any, of the retail package of the article, or is easily legible through the
32 outside container or wrapper.

33 (ii) "Immediate container" does not include package liners.

34 (iii) "Labeling" means all labels and other written, printed, or graphic matter: (A) upon

1 an article or any of its containers or wrappers, or (B) accompanying the article.

2 (iv) If an article is alleged to be misbranded because the labeling is misleading, or if an
3 advertisement is alleged to be false because it is misleading, then in determining whether the
4 labeling or advertisement is misleading there shall be taken into account (among other things) not
5 only representations made or suggested by statement, word, design, device, sound, or in any
6 combination of them, but also the extent to which the labeling or advertisement fails to reveal
7 facts material in the light of the representations or material with respect to consequences which
8 may result from the use of the article to which the labeling or advertisement relates under the
9 conditions of use prescribed in the labeling or advertisement or under the conditions of use that
10 are customary or usual.

11 (14) "Native" means a product harvested in Rhode Island and is limited to the following:

12 (i) "Bay scallop" means *Argopecten irradians*.

13 (ii) "Bay quahog" means *Mercenaria mercenaria*.

14 (iii) "Steamer clams" means *Mya arenaria*.

15 (iv) "Mussels" means *Mytilus edulis*.

16 (v) "Oysters" means *Crassostrea virginica*.

17 (15) "New drug" means: (i) any drug the composition of which is such that the drug is
18 not generally recognized among experts qualified by scientific training and experience to evaluate
19 the safety of drugs as safe for use under conditions prescribed, recommended, or suggested in the
20 labeling of it; or (ii) any drug the composition of which is such that the drug, as a result of
21 investigations to determine its safety for use under those conditions has become so recognized,
22 but which has not, otherwise than in the investigations, been used to a material extent or for a
23 material time under those conditions.

24 (16) "Official compendium" means the official United States Pharmacopoeia, official
25 Homeopathic Pharmacopoeia of the United States, official National Formulary, or any
26 supplement to any of them.

27 (17) "Patient" means, as the case may be: (i) the individual medically requiring a drug,
28 for whom a drug is prescribed; or (ii) the owner or the agent of the owner of an animal medically
29 requiring a drug, for which a drug is prescribed.

30 (18) "Person" includes individual, partnership, corporation, and association.

31 (19) "Pharmacist" means a person duly registered with the board of pharmacy as a
32 compounder, dispenser, or supplier of drugs upon prescription, including registered assistant
33 pharmacists as defined by law.

34 (20) "Pharmacy" means a place where drugs, medicines, or poisons are sold at retail or

1 where prescriptions of physicians, dentists, veterinarians, and other practitioners authorized to
2 issue prescriptions for drugs, medicines, and poisons are compounded, dispensed, supplied or
3 sold.

4 (21) "Practitioner" means a person authorized by law to practice medicine, dentistry,
5 osteopathy, chiropractic, or veterinary medicine in this state.

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

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

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

26 SECTION 2. Chapter 21-31 of the General Laws entitled "Rhode Island Food, Drugs,
27 and Cosmetics Act" is hereby amended by adding thereto the following section:

28 **21-31-18.1. Cosmetic ingredient disclosure.** -- (a) Beginning January 1, 2017, any
29 cosmetic manufactured, distributed or offered for retail sale in this state shall disclose on the
30 product label and on the manufacturer's Internet website the full list of ingredients in the product,
31 including the component ingredients of fragrances, flavors and color additives. The Chemical
32 Abstract Service (CAS) number of each ingredient shall be included on the ingredient list
33 provided on the manufacturer's Internet website.

34 (b) The ingredients shall be listed in descending order of predominance, except that an

1 ingredient present at a concentration of not more than one percent may be listed without respect
2 to order of predominance.

3 (c) The manufacturer is not required to list the concentration of an ingredient in the
4 product on the label or on the manufacturer's Internet website.

5 (d) A cosmetic ingredient shall be identified in the declaration of ingredients in
6 accordance with Part 701.3(c) of the Code of Federal Regulations, referred to as 21 CFR
7 701.3(c).

8 (e) If any person violates any provision of this section, or any regulation adopted
9 pursuant to this section, the director shall assess a fine of not less than ten thousand dollars
10 (\$10,000) per violation. If such violation is not corrected within six (6) months of the initial
11 violation, the manufacturer shall be fined not less than twenty-five thousand dollars (\$25,000).

12 SECTION 3. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

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1 This act would require manufacturers to fully disclose all ingredients of their cosmetics
2 on their product label, as well as on their website. Failure to do so would result in a substantial
3 fine.

4 This act would take effect upon passage.

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