

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

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A N A C T

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

Introduced By: Senators Coyne, Calkin, Satchell, Goldin, and DiPalma

Date Introduced: April 04, 2017

Referred To: Senate Health & Human Services

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.**

4 For the purpose of this chapter:

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

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

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

16 (4) "Device" (except when used in subdivision (23) of this section and in §§ 21-31-3(10),
17 21-31-11(6), 21-31-15(a)(3), and 21-31-18(3)) means instruments, apparatus, and contrivances,
18 including their components, parts, and accessories, intended: (i) for use in the diagnosis, cure,

1 mitigation, treatment, or prevention of disease in humans or other animals; or (ii) to affect the
2 structure or any function of the body of humans or other animals.

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

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

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

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

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

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

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

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

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

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

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

1 (iii) "Labeling" means all labels and other written, printed, or graphic matter: (A) upon an
2 article or any of its containers or wrappers, or (B) accompanying the article.

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

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

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

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

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

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

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

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

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

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

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

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

1 (20) "Pharmacy" means a place where drugs, medicines, or poisons are sold at retail or
2 where prescriptions of physicians, dentists, veterinarians, and other practitioners authorized to
3 issue prescriptions for drugs, medicines, and poisons are compounded, dispensed, supplied or
4 sold.

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

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

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

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

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

29 **21-31-18.1. Cosmetic ingredient disclosure.**

30 (a) The manufacturer of any cosmetic product manufactured, distributed, or offered for
31 retail or sale in this state shall disclose to the department of health a list of the fragrance
32 ingredients in the product. The manufacturer shall include the chemical abstract service (CAS)
33 number of each ingredient on the list provided to the department.

34 (b) The department of health shall disclose on a searchable website information received

1 pursuant to this act.

2 (c) The ingredients shall be listed in descending order of predominance, except that an
3 ingredient present in a product at a concentration of one percent (1%) or less may be listed
4 without respect to the order of predominance after the list of ingredients present at concentrations
5 of more than one percent (1%).

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

10 SECTION 3. This act shall take effect on January 1, 2018.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

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

1 This act would require manufacturers to fully disclose to the department of health all
2 ingredients contained in their cosmetic products manufactured, distributed or sold in the state, and
3 would further subject a manufacturer to financial penalties for a violation of this requirement.

4 This act would take effect on January 1, 2018.

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