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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2015

A N A C T

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

Introduced By: Representatives Handy, Maldonado, Tanzi, Regunberg, and Edwards

Date Introduced: February 26, 2015

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Section 21-31-2 of the General Laws in Chapter 21-31 entitled "Rhode Island Food, Drugs, and Cosmetics Act" is 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) "Biodegradable" means the capability of a substance to break down completely in the natural environment that the substance is likely to encounter within twenty-four (24) months of its disposal, through a biological process of decomposition into elements or compounds commonly found in that environment.

~~(2)~~(3) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

~~(3)~~(4) "Cosmetics" means: (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or applied to the humanbody or any part of the body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (ii) articles intended for use as a component of any articles described in this subdivision, except that this term shall not include soap.

~~(4)~~(5) "Device" (except when used in subdivision ~~(23)~~ (28) of this section and in §§ 21-31-3(10), 21-31-11(6), 21-31-15(a)(3), and 21-31-18(3)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended: (i) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or (ii) to affect the structure or any function of the body of humans or other animals.

~~(5)~~(6) "Director" means the director of health.

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

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

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

~~(9)~~(10) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

~~(10)~~(11) (i) "Equivalent and interchangeable" means having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the department of health.

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

~~(11)~~(12) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

~~(12)~~(13)"Food" means: (i) articles used for food or drink for humans or other animals, (ii) chewing gum, and (iii) articles used for components of any article described in this subdivision.

(14) "Household cleansing product" means any product, including soaps and detergents used for domestic or commercial cleaning purposes, including the cleansing of fabric, dishes,

food utensils, and household and commercial premises. Household cleansing product shall not mean:

(i) Food, drugs, and cosmetics, including personal care items such as toothpaste, shampoo, and hand soap;

(ii) Products labeled, advertised, marketed, and distributed for use primarily as economic poisons.

~~(13)~~(15) (i) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appearing on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of the article, or is easily legible through the outside container or wrapper.

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

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

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

~~(14)~~(16) "Native" means a product harvested in Rhode Island and is limited to the following:

(i) "Bay scallop" means Argopecten irradians.

(ii) "Bay quahog" means Mercenaria mercenaria.

(iii) "Steamer clams" means Mya arenaria.

(iv) "Mussels" means Mytilus edulis.

(v) "Oysters" means Crassostrea virginica.

~~(15)~~(17) "New drug" means: (i) any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use under conditions prescribed, recommended, or

suggested in the labeling of it; or (ii) any drug the composition of which is such that the drug, as a result of investigations to determine its safety for use under those conditions has become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under those conditions.

~~(16)~~(18) "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(19) "Over-the-counter drug" means a compound, substance, or preparation that contains a label that identifies the product as a drug, as required by 21 C.F.R. § 201.66, and that includes a drug facts panel or a statement of the active ingredient or ingredients contained in the compound, substance, or preparation.

~~(17)~~(20) "Patient" means, as the case may be: (i) the individual medically requiring a drug, for whom a drug is prescribed; or (ii) the owner or the agent of the owner of an animal medically requiring a drug, for which a drug is prescribed.

~~(18)~~(21) "Person" includes individual, partnership, corporation, and association.

(22) "Personal care product" means any article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and any article intended for use as a component of any such article. "Personal care product" shall not include any prescription drug.

~~(19)~~(23) "Pharmacist" means a person duly registered with the board of pharmacy as a compounder, dispenser, or supplier of drugs upon prescription, including registered assistant pharmacists as defined by law.

~~(20)~~(24) "Pharmacy" means a place where drugs, medicines, or poisons are sold at retail or where prescriptions of physicians, dentists, veterinarians, and other practitioners authorized to issue prescriptions for drugs, medicines, and poisons are compounded, dispensed, supplied or sold.

(25) "Plastic" means a synthetic material made from linking monomers through a chemical reaction to create an organic polymer chain that can be molded or extruded at high heat into various solid forms retaining their defined shapes during its life cycle and after disposal.

~~(21)~~(26) "Practitioner" means a person authorized by law to practice medicine, dentistry, osteopathy, chiropody, or veterinary medicine in this state.

~~(22)~~(27) "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.

(28) "Synthetic plastic microbead" means an intentionally added nonbiodegradable solid plastic particle less than five (5) millimeters in size.

~~(23)~~(29) 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)~~(30) The provisions of this chapter regarding the selling of food, drugs, devices, household cleansing products 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.

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:

21-31-18.1. Prohibition of personal care products, over-the-counter drugs, microbeads and household cleansing products. – (a) Findings. – The general assembly finds:

(1) Microbeads are a synthetic alternative ingredient in personal care products and over-the-counter drugs that are used in place of natural materials such as ground almonds, oatmeal, and pumice.

(2) Microbeads are found in over one hundred (100) personal care products and over-the-counter drugs that are sold in the state and that ultimately are flushed down drains as part of the intended use of the product.

(3) Most municipal wastewater treatment plants in the state do not effectively filter microbeads from water discharged to rivers and lakes.

(4) Plastic microbeads are persistent inorganic compounds that attract other pollutants commonly present in the environment, many of which are recognized to have serious deleterious

impacts on human health or the environment, including dichlorodiphenyltrichloroethane (DDT), dichlorodiphenyldichloroethylene (DDE), polychlorinated biphenyl (PCBs), and flame-retardants.

(5) Chemicals from plastics, such as PCBs, polycyclic aromatic hydrocarbons (PAHs), and polybrominated diphenyl ethers (PBDEs), transfer to fish tissue during digestion, bioaccumulate, and result in liver damage.

(6) Fish consumed by humans have been found to have ingested plastic microbeads.

(7) There are economically feasible alternatives to plastic microbeads, as indicated by the current use of biodegradable, natural, and abrasive materials in many consumer personal care products.

(8) Updating municipal wastewater treatment plants so that they effectively filter microbeads likely would be costly and take many years.

(9) To prevent the continued harmful effects of microbeads on state waters without expending significant time and money to update wastewater treatment plants, synthetic microbeads should be banned from manufacture and sale in the state.

(b) Manufacture of personal care products. Beginning on December 31, 2017, no person shall manufacture in the state a personal care product that contains synthetic plastic microbeads, except for an over-the-counter drug.

(c) Sale of personal care products. Beginning on December 31, 2018, no person shall sell, offer for sale, offer for promotion, or otherwise distribute in the state a personal care product that contains synthetic plastic microbeads, except for an over-the-counter drug.

(d) Manufacture of over-the-counter drugs. Beginning on December 31, 2018, no person shall manufacture in the state an over-the-counter drug containing synthetic plastic microbeads.

(e) Sale of over-the-counter drugs. Beginning on December 31, 2019, no person shall sell, offer for sale, offer for promotion, or otherwise distribute in the state an over-the-counter drug that contains synthetic plastic microbeads.

(f) Household cleansing products.

(1) No household cleansing products containing a phosphorus compound in concentrations in excess of a trace quantity may be distributed, sold, offered for sale at retail or wholesale, exposed for sale at retail or wholesale, or used in a commercial establishment in this state, except as set forth in subdivisions (2) and (3) of this subsection.

(2) No household cleansing product used in a dishwasher in a commercial establishment, used to cleanse food and beverage processing equipment, including dishes, pots, pans and utensils, used to cleanse medical or surgical equipment, or used to cleanse dairy equipment may be distributed, sold, offered for sale at retail or wholesale, exposed for sale at retail or wholesale,

or used in a commercial establishment if it contains a phosphorus compound in concentrations in excess of eight and seven tenths percent (8.7%) by weight expressed as elemental phosphorus.

(3) As of July 1, 2016, no household cleansing product used in a residential dishwasher may be distributed, sold, offered for sale at retail or wholesale, or exposed for sale at retail or wholesale if it contains a phosphorus compound in concentrations in excess of a trace quantity, except for product inventory purchased by retailers prior to July 1, 2016.

(4) The provisions of this subsection shall not be construed to limit the phosphorus content of household cleansing products used in agricultural production and for cleansing equipment used in processing agricultural products.

(5) The provisions of this subsection shall not be construed to limit the phosphorus content of household cleansing products approved by the commissioner of health for use in lead hazard management projects.

SECTION 3. This act shall take effect on July 1, 2015.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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

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This act would prohibit the manufacture and sale of personal care products, over-the-counter drugs, microbeads and household cleansing products containing synthetic plastic microbeads or phosphorus gradually from July 1, 2016 though December 31, 2019.

This act would take effect on July 1, 2015.

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