THE SENATE
TWENTY-SEVENTH LEGISLATURE, 2014
STATE OF HAWAII

S.B. NO. 2067

JAN 15 2014

A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Section 328-1, Hawaii Revised Statutes, is amended by adding two new definitions to be appropriately inserted and to read as follows:

""Dietary supplement" has the same meaning as in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

"Good manufacturing practices for dietary supplements" means requirements for the manufacturing, packaging, labeling, or holding of dietary supplements as stated in title 21 C.F.R. part 111."

SECTION 2. Section 328-6, Hawaii Revised Statutes, is amended to read as follows:

"**§328-6 Prohibited acts.** The following acts and the causing thereof within the State by any person are prohibited:

(1) The manufacture, sale, delivery, holding, or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

(2) The adulteration or misbranding of any food, drug, device, or cosmetic;

(3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 328-11, 328-12, or 328-17;

(5) The dissemination of any false advertisement;

(6) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by sections 328-22 and 328-23 to 328-27, or to permit access to or copying of any record as authorized by section 328-23;

(7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State from whom the person received in good faith the food, drug, device, or cosmetic;

(8) The removal or disposal of a detained or embargoed article in violation of sections 328-25 to 328-27;

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being adulterated or misbranded;

(10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part or regulations adopted under the Federal Act;

(11) The use, on the labeling of any drug or in any advertisement relating to the drug, of any representation or suggestion that an application with respect to the drug is effective under section 328-17, or that the drug complies with that section;

(12) The use by any person to the person's own advantage, or revealing other than to the department of health or to the courts when relevant in any judicial proceeding

under this part, any information acquired under authority of section 328-11, 328-12, 328-17, or 328-23, concerning any method or process which as a trade secret is entitled to protection;

(13) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner who makes written request for information as to the drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part;

(14) (A) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; [~~or~~]

(B) Selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subparagraph (A); or

(C) Making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof;

(15) Except as provided in part VI and section 461-1, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug

ordered or prescribed without express permission in each case of the person ordering or prescribing;

(16) The distribution in commerce of a consumer commodity as defined in this part, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to this part and of rules adopted under authority of this part; provided that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:

(A) Are engaged in the packaging or labeling of such commodities; or

(B) Prescribe or specify by any means the manner in which such commodities are packaged or labeled;

(17) The selling or dispensing in restaurants, soda fountains, drive-ins, lunch wagons, or similar public eating establishments of imitation milk and imitation milk products in place of fresh milk and fresh milk products respectively; of liquid or dry products which simulate cream but do not comply with content requirements for cream in place of cream; of non-dairy

frozen desserts which do not comply with content requirements for dairy frozen desserts in place of dairy frozen desserts; and of any other imitation food or one made in semblance of a genuine food in place of such genuine food, unless the consumer is notified by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements informing of such substitution, to include but not limited to the substitution of imitation milk in milk shake and malted milk drinks;

(18) Wilfully and falsely representing or using any devices, substances, methods, or treatment as effective in the diagnosis, cure, mitigation, treatment, or alleviation of cancer. This paragraph shall not apply to any person who depends exclusively upon prayer for healing in accordance with teachings of a bona fide religious sect, denomination, or organization, nor to a person who practices such teachings;

(19) The selling or offering for sale at any food facility which serves or sells over the counter directly to the consumer an unlabeled or unpackaged food that is a

confectionery which contains alcohol in excess of one-half of one per cent by weight unless the consumer is notified of that fact by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements;

(20) The sale to a person below the age of twenty-one years of any food which is a confectionery which contains alcohol in excess of one-half of one per cent by weight [~~.~~]; or

(21) The sale, delivery for sale, holding for sale, or offering for sale of any dietary supplement that does not conform to the federal good manufacturing practices for dietary supplements."

SECTION 3. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 4. This Act shall take effect upon its approval.

INTRODUCED BY: _____

S.B. NO. 2067

Report Title:
Health; Dietary Supplements; Food, Drug, and Cosmetic Act; Good Manufacturing Practices

Description:
Establishes that it is a prohibited act under Hawaii's Food, Drug, and Cosmetic Act to sell, deliver for sale, hold for sale, or offer for sale any dietary supplement that does not conform to federal good manufacturing practices for dietary supplements.

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