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# A BILL FOR AN ACT

RELATING TO HEALTH.

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

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

4           "Dietary supplement" has the same meaning as in section  
5 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 321).

7           "Good manufacturing practices for dietary supplements"  
8 means requirements for the manufacturing, packaging, labeling,  
9 or holding of dietary supplements as stated in title 21 Code of  
10 Federal Regulations part 111."

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

13          "**§328-6 Prohibited acts.** The following acts and the  
14 causing thereof within the State by any person are prohibited:

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



- 1           (2) The adulteration or misbranding of any food, drug,  
2           device, or cosmetic;
- 3           (3) The receipt in commerce of any food, drug, device, or  
4           cosmetic that is adulterated or misbranded, and the  
5           delivery or proffered delivery thereof for pay or  
6           otherwise;
- 7           (4) The sale, delivery for sale, holding for sale, or  
8           offering for sale of any article in violation of  
9           section 328-11, 328-12, or 328-17;
- 10          (5) The dissemination of any false advertisement;
- 11          (6) The refusal to permit entry or inspection, or to  
12          permit the taking of a sample, as authorized by  
13          sections 328-22 and 328-23 to 328-27, or to permit  
14          access to or copying of any record as authorized by  
15          section 328-23;
- 16          (7) The giving of a guaranty or undertaking which guaranty  
17          or undertaking is false, except by a person who relied  
18          on a guaranty or undertaking to the same effect signed  
19          by, and containing the name and address of the person  
20          residing in the State from whom the person received in  
21          good faith the food, drug, device, or cosmetic;



- 1 (8) The removal or disposal of a detained or embargoed  
2 article in violation of sections 328-25 to 328-27;
- 3 (9) The alteration, mutilation, destruction, obliteration,  
4 or removal of the whole or any part of the labeling  
5 of, or the doing of any other act with respect to a  
6 food, drug, device, or cosmetic, if the act is done  
7 while the article is held for sale and results in the  
8 article being adulterated or misbranded;
- 9 (10) Forging, counterfeiting, simulating, or falsely  
10 representing, or without proper authority using any  
11 mark, stamp, tag, label, or other identification  
12 device authorized or required by rules adopted under  
13 this part or regulations adopted under the Federal  
14 Act;
- 15 (11) The use, on the labeling of any drug or in any  
16 advertisement relating to the drug, of any  
17 representation or suggestion that an application with  
18 respect to the drug is effective under section 328-17,  
19 or that the drug complies with that section;
- 20 (12) The use by any person to the person's own advantage,  
21 or revealing other than to the department of health or  
22 to the courts when relevant in any judicial proceeding



1 under this part, any information acquired under  
2 authority of section 328-11, 328-12, 328-17, or  
3 328-23, concerning any method or process which as a  
4 trade secret is entitled to protection;

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

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



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

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

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



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

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

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

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

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



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

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

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



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

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

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

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

16 SECTION 4. This Act shall take effect on January 1, 2050.





**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. Effective 1/1/2050. (SD1)

*The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.*

