## ACT 151 S. B. NO. 46

A Bill for an Act Relating to the Hawaii Food, Drug, and Cosmetic Act.

*Be It Enacted by the Legislature of the State of Hawaii:*

SECTION 1. Section 328-1, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-1 Definitions.** For the purposes of this part:

(1) 'Department' means the department of health;

(2) 'Federal Act' means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040; 21 USC 3.01 et seq.);

(3) 'Food' means (A) articles used for food or drink for man or animals, (B) chewing gum, and (C) articles used for components of any such article;

(4) 'Drug' means (A) 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; (B) article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in man or animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C), but does not include devices or their components, parts or accessories;

(5) 'Device', except when used (e.g. as an indentification device in labeling) in sections 328-3(a), 328-6(10), 328-10(6), 328-15(3), and 328-19(3), means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (A) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or (B) to affect the structure or any function of the body of man or animals;

(6) 'Cosmetic' means (A) articles 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 (B) articles intended for use as a component of any such articles, except that the term shall not include soap intended for cleansing purposes only;

(7) '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.

(8) 'Pesticide chemical' means any substance which, alone, in chemical combination, or in formulation with one or more other substances is an 'economic poison' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., §§135-135k) as now enacted or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities;

(9) 'Raw agricultural commodity' means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(10) 'Food additive' means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, except that the term does not include:
(A) A pesticide chemical in or on a raw agricultural commodity; or
(B) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
(C) A color additive; or
(D) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal Act, the Poultry Products Inspection Act (21 U.S.C. 451ff), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71ff);

(11) (A) 'Color additive' means a material which:
(i) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source, or
(ii) When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that the term does not include any material which has been or hereafter is exempted under the Federal Act.
(B) The term 'color' includes black, white, and intermediate grays.
(C) Nothing in clause (A) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

(12) 'Consumer commodity' as herein defined means any food, drug, cosmetic or device as those terms are defined by, this part or, the Federal Act.

Such term shall not include:

(1) Any meat or meat product or poultry or poultry product or tobacco or tobacco product;

(2) Any commodity subject to packaging and labeling requirements imposed by the Secretary of Agriculture pursuant to the Federal Insecticide, Fungicide and Rodenticide Act or the provisions of the eighth paragraph under the heading 'Bureau of Animal Industry' of the Act of March 4, 1913 (37 Stat 832-833; 21 USC 151-157), commonly known as the Virus-Serum-Toxin Act;

(3) Any drug subject to the provisions of Section 503 (b) (1) or 506 of the Federal Food, Drug and Cosmetic Act (21 USC 353 (b) (1) and 356);

(4) Any beverage subject to or complying with packaging and labeling requirements imposed under the Federal Alcohol Administration Act (27 USC 201 et seq.); or

(5) Any commodity subject to the provisions of the Federal Seed Act (7 USC 1551-1610).

(13) 'Director' means the director of health of the State of Hawaii."

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

**"Sec. 328-2 Same; label, etc.** '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 part that any word, statement, or other information appear 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 there be, of the retail package of the article, or is easily legible through the outside container or wrapper.

'Immediate container' does not include package liners.

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

'Package' means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include (1) shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; (2) shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.

'Principal Display panel' means that part, or those parts, of a package or label that is, or are, so designed as to most likely be displayed, presented, shown or examined under normal and customary conditions of display and purchase.

Whenever the principal display panel of the package is not coincident with the principal display panel of the label, the principal display panel of the package shall govern the declaration of quantity type size and the principal display panel of the label shall govern its location.

Whenever a difference of opinion exists as to which panel of a package constitutes the principal display panel, the larger panel most likely to be displayed shall be so construed.

Whenever a consumer package has more than one principal display panel, each such panel shall bear all mandatory information required by this part and by Chapter 486, H.R.S., as amended, the Weights and Measures and Uniform Packaging and Labeling Act.

**"Sec. 328-2.1 Applicability to the State Weights and Measures and Uniform Packaging and Labeling Act.**

(1) Nothing herein contained shall be construed to limit, alter, transfer or otherwise diminish the functions, duties, powers and responsibilities of the director of weights and measures relative to the administration and enforcement of the State Weights and Measures and Uniform Packaging and Labeling Act, Chapter 486, H.R.S., as amended; nor the director of health respecting the Hawaii Food, Drug and Cosmetic Act.

(2) Respecting the quantitative and packaging and labeling aspects of Chapter 486, H.R.S., as amended, and the requirements of any applicable rule promulgated pursuant thereto, Chapter 486, H.R.S., as amended, shall prevail. Any part herein, or other laws or parts of laws to the contrary notwithstanding, and particularly section 32 of Chapter 486, H.R.S., as amended, which is hereby repealed.

(3) In all cases where the respective directors ascertain that a 'consumer commodity', as herein defined, has been misbranded, they shall forthwith exchange all data and copies of pertinent information, to the expeditious resolution of the problem."

SECTION 3. Section 328-6, Hawaii Revised Statutes, is amended to read:

**"Sec. 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 sections 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, 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 he 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 regulations promulgated under this part or the Federal Act;

(11) The using, 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 the provisions of such section;

(12) The using by any person to his 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 sections 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 licensed by applicable law to administer the drug 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 clause (A) hereof; 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) 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 the provisions of this part and of regulations promulgated 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 (1) are engaged in the packaging or labeling of such commodities, or (2) prescribe or specify by any means the manner in which such commodities are packaged or labeled."

SECTION 4. Section 328-8, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-8 Regulations to be prescribed.** Whenever in the judgment of the department of health such action will promote honesty and fair dealing in the interest of consumers, the department shall prescribe regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, or reasonable standard of quality or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the department shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so prescribed shall conform so far as practicable to the definitions and standards promulgated under authority of the federal act.

"Temporary permits now or hereafter granted for interstate shipment of experimental packs of food varying from the requirements of Federal definitions and standards of identity are automatically effective in this State under the conditions provided in such permits. In addition, the director may issue additional permits where they are necessary to the completion or conclusiveness of an otherwise adequate investigation and where the interests of consumers are safeguarded. Such permits shall be subject to such terms and conditions as the director may prescribe."

SECTION 5. Section 328-10, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-10. Foods deemed misbranded when.** A food shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular; or if its labeling or packaging fails to conform with the requirements of sections 328-2, 328-2.1 and 328-19.1;
(2) If it is offered for sale under the name of another food;
(3) If it is an imitation of another food for which a definition and standard of identity has been prescribed by regulation as provided by section 328-8; or if it is an imitation of another food that is not subject to paragraph (7) of this section, unless its label bears in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated;
(4) If its container is so made, formed, or filled as to be misleading;
(5) If in package form, unless it bears a label containing (A) the name and place of business of the manufacturer, packer, or distributor; (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location under the principal display panel of the label; provided, that under clause (B) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the department of health;
(6) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
(7) If it purports to be or is represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by section 328-8, unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standards, and, insofar as may be required by the regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in the food;
(8) If it purports to be or is represented as:
  (A) A food for which a standard of quality has been prescribed by regulations as provided by section 328-8 and its quality falls below such standard unless its label bears, in such manner and form as the regulations specify, a statement that it falls below such standard; or
  (B) A food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 328-8, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as the regulations specify, a statement that it falls below such standard;
(9) If it is not subject to paragraph (7) of this section, unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the com-

mon or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each; provided, that, to the extent that compliance with the requirements of clause (B) of this paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations prescribed by the department; and, provided, further, that the requirements of clause (B) shall not apply to food products which are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations prescribed by the department;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the department determines to be, and by regulations prescribes, as necessary in order to fully inform purchasers as to its value for such uses;

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; provided, that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations prescribed by the Department; and, provided, further, that this paragraph and paragraphs (7) and (9) of this section with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph regarding chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil;

(12) If it is a product intended as an ingredient of another food and, when used according to the directors of the purveyor, will result in the final food product being adulterated or misbranded;

(13) If it is a color additive unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to the color additive prescribed under the Federal Act;

(14) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical; provided that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade."

SECTION 6. Chapter 328, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read:

"**Sec. 328- . Regulations for exemption from labeling requirements.** The director may adopt regulations exempting from any labeling requirement of this part food which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other

than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this part upon removal from such processing, labeling or repacking establishment."

SECTION 7. Section 328-13(a), Hawaii Revised Statutes, is amended to read:

"**Sec. 328-13. Adding of poisonous or deleterious substance, regulation of.** (a) Any added poisonous or deleterious substance, and food additive, any pesticide chemical in or on a raw agricultural commodity, or any color additive, shall, with respect to any particular use or intended use, be deemed unsafe for the purpose of application of clause (B) (i) of section 328-9(1) with respect to any food, section 328-14(1) with respect to any drug or device, or section 328-18(1) with respect to any cosmetic, unless there is in effect a regulation pursuant to section 328-18.1, or subsection (b) of this section limiting the quantity of the substance, and the use or intended use of the substance conform to the terms prescribed by the regulation. While the regulation relating to such substance is in effect, a food, drug, or cosmetic shall not, by reason of bearing or containing the substance in accordance with the regulation, be considered adulterated within the meaning of section 328-9(1) (A), section 328-14(1), or section 328-18(1)."

SECTION 8. Section 328-15, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-15. Drugs or devices deemed misbranded when; prescriptions excepted, when.** A drug or device shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of section 328-19.1.

(2) If in package form, unless it bears a label containing

(A) The name and place of business of the manufacturer, packer, or distributor; and

(B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label, except as exempted with respect to this clause by section 328-1(12) (3); provided, that under clause (B) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the director of health.

(3) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine, codine, heroin

marihuana, morphine, opium, paraldehyde, peyote, or sulphomethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as, habit-forming, by regulations issued by the director under this part, or by regulations issued pursuant to section 502(d) of the Federal Act, unless its label bears the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit-forming.'

(5) (A) If it is a drug unless (1) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name, as defined in subparagraph (B), of the drug, if such there be; and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (2) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; provided further, that to the extent that compliance with the requirements of clause (1) (ii) or clause (2) of this subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the director.

(B) As used in this paragraph (5) the term 'established name' with respect to a drug or ingredient thereof, means

(i) The applicable official name designated pursuant to section 508 of the Federal Act, or

(ii) If there is no such name and the drug, or the ingredient, is an article recognized in an official compendium, then the official title thereof in the compendium or

(iii) If neither clause (i) nor clause (ii) of this subparagraph applies, then the common or usual name, if any, of such drug or of the ingredient;

provided further, that where clause (ii) of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the

United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

(6) Unless its labeling bears
  (A) Adequate directions for use; and
  (B) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; provided, that where any requirement of clause (A) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the director shall promulgate regulations exempting the drug or device from such requirements; provided further, that articles exempted under regulations issued under section 502 (f) of the Federal Act may also be exempt.

(7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided, that the method of packing may be modified with the consent of the director, or if consent is obtained under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopeoia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to the packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia; provided further, that in the event of inconsistency between the requirements of this paragraph and those of paragraph (5) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (5) shall prevail.

(8) If it has been found by the director to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the regulations issued by the director or under the Federal Act require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the director shall have informed the appropriate body charged with the revision of the compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(9) (A) If it is a drug and its container is so made, formed, or filled as to be misleading; or
  (B) If it is an imitation of another drug; or
  (C) If it is offered for sale under the name of another drug;

(10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

(11) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless

(A) It is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the Federal Act, and

(B) The certificate or release is in effect with respect to the drug.

(12) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless

(A) It is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the Federal Act, and

(B) The certificate or release is in effect with respect to the drug; provided, that this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the Federal Act. For the purpose of this subsection the term 'antibiotic drug' means any drug intended for use by man containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including the chemically synthesized equivalent of any such substance);

(13) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to such color additive prescribed under section 328-13(b);

(14) In the case of any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of

(A) The established name, as defined in paragraph (5) (B), printed prominently and in type at least half as large as that used for any trade or brand name thereof,

(B) The formula showing quantitatively each ingredient of the drug to the extent required for labels under section 502(e) of the Federal Act, and

(C) Such other information in brief summary relating to side effects, contra-indications, and effectiveness as shall be required in regulations issued by the director;

(15) If a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud;

(16) Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed

or packed shall be exempt from any labeling or packaging requirements of this part, provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with regulations issued by the director."

SECTION 9. Section 328-16(a), Hawaii Revised Statutes, is amended to read:

"**Sec. 328-16 Drugs limited to dispensing on prescription.** (a) A drug intended for use by man which (1) is a habit-forming drug to which section 328-15(4) applies; or (2) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or (3) is limited by an approved application under section 505 of the Federal Act or section 328-17 to use under the professional supervision of a practitioner licensed by law to administer the drug, shall be dispensed only (A) upon a written prescription of a practitioner licensed by law to administer the drug, or (B) upon an oral prescription of the practitioner, provided, the seller promptly records in his books the oral prescription in full, the kind, quantity of the drug, and directions for use, the date the oral prescription is received, the name of the seller, the name and code designation of the prescriber, and the name and address of the person for whom the drug is prescribed or the name of the owner of the animal for which the drug is prescribed, the department of health assigning such code designation to such subscriber, and such books being subject at all times to the inspection of the department or its agents, or (C) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist, and (D) its label bears the name and place of business of the seller, the serial number and date of the prescription, and the name of the practitioner. If any prescription for such drug does not indicate the time it may be refilled, if any, such prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner. The act of dispensing a drug contrary to this subsection shall be deemed to be an act which results in a drug being misbranded while held for sale."

SECTION 10. Section 328-17, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-17 New drugs, regulation of sale, etc.; exceptions.** (a) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under section 505 of the Federal Act, or (2) when not subject to the Federal Act, unless the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale the drug, there has been filed with the director of health an application setting forth (A) full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use; (B) a full list of the articles used as components of the drug;

(C) a full statement of the composition of the drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drugs; (E) such samples of the drug and of the articles used as components thereof as the director may require; and (F) specimens of the labeling proposed to be used for the drug.

(b) An application provided for in subsection (a) (2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the director finds, after due notice to the applicant and giving him an opportunity for a hearing, (1) that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or (2) the methods used in, and the facilities and controls used for the manufacture, processing, and packing of such drugs are inadequate to preserve its identity, strength, quality, and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the director.

(d) The director shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the director, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon: (1) the submission to the director before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and (3) the establishment and maintenance of such records, and the making of such reports to the director by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drugs, as the director finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b). Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any person to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such person or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such person.

(e) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the application shall establish and maintain such records, and make such reports to the director, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drugs, as the director may by regulation, or by order with respect to such application, prescribe; provided that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the director deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the director.

Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the director permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(f) The director may, after affording an opportunity for hearing, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health."

SECTION 11. Section 328-19, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-19 Cosmetics deemed misbranded when.** A cosmetic shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of section 328-19.1 of this part;

(2) If in package form, unless it bears a label containing (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label; provided, that under clause (B) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the director;

(3) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) If its container is so made, formed or filled as to be misleading;

(5) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to the color additive prescribed under the Federal Act. This paragraph

shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 328-18(1);

(6) Unless it is a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed. Such cosmetic is exempted from the affirmative labeling requirements of this Part while it is in transit in commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all applicable provisions of this part."

SECTION 12. Chapter 328, Hawaii Revised Statutes, is amended by adding a new section to read:

"**Sec. 328-19.1 Consumer commodities; labeling; packaging.** (a) All labels of consumer commodities, as defined by this part, shall conform with the requirements for the declaration of net quantity of contents of Section 4 of the Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.) and the regulations promulgated pursuant thereto; provided that consumer commodities exempted from such requirements of Section 4 of the Fair Packaging and Labeling Act shall also be exempt from this subsection;

(b) The label of any package of a consumer commodity which bears a representation as to the number of servings of such commodity contained in such package shall bear a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving.

(c) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by subsection (a), but nothing in this section shall prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents; provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.

(d) Wherever the director determines that regulations containing prohibitions or requirements other than those prescribed by subsection (a) of this section are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, the director shall promulgate with respect to that commodity regulations effective to: (1) establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity but this paragraph shall not be construed as authorizing any limitation on the size, shape, weight, dimensions, or number of packages which may be used to enclose any commodity; (2) regulate the placement upon any package containing any commodity, or upon any label affixed to such commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and

customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents; (3) require that the label on each package of a consumer commodity bear (A) the common or usual name of such consumer commodity, if any, and (B) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged; or (4) prevent the nonfunctional slack-fill of packages containing consumer commodities.

For the purposes of clause (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reason other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such packages."

SECTION 13. Section 328-23, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-23. Inspection powers of director.** The director or any of his agents are authorized upon presenting appropriate credentials to the owner, operator or agent in charge, (1) to enter at all reasonable hours any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in commerce; (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein to determine if this part is being violated; (3) to have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof; provided that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this part by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers; and (4) to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for the sample. The director shall make or cause to be made examinations of samples secured under this section to determine whether or not this part is being violated."

SECTION 14. Section 328-25, Hawaii Revised Statutes, is amended to read:

"**Sec. 328-25. Director's right of inspection and seizure; hearings.** The director or any of his agents may in the performance of their duties enter at all reasonable hours into any creamery, factory, restaurant, store, salesroom, storage-room, drug store, or laboratory, or any place where they have probable cause to believe that food, drugs, devices, cosmetics, or consumer commodity as defined by this part are made, prepared, sold, or kept, exhibited or offered

for sale, and open any cask, tub, bottle, case or package containing or supposed to contain any such food, drug, device, cosmetic, or consumer commodity, and examine or cause to be examined the contents thereof. In case any food, drug, device, cosmetic, or consumer commodity is found to be adulterated or misbranded within the meaning of this part and the owner or person in charge thereof refuses to comply with the instructions of the director or any of his agents for the proper disposal thereof, the food, drug, device, cosmetic, or consumer commodity shall be liable to seizure. The director or any of his agents shall affix to the article or articles a tag or other appropriate marking, giving notice that the article is, or is suspected of being adulterated or misbranded, and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or any of his agents or by the court or judge having jurisdiction over such matters. Upon the request of the director or any of his agents, made to such court, the court shall order and direct that the food, drug, device, cosmetic or consumer commodity be seized and delivered into the custody of the court, and the same shall be held in such custody until a hearing has been held to determine whether or not it is adulterated or misbranded."

SECTION 15. Material to be repealed is bracketed. New material is underscored. In printing this Act, the revisor of statutes need not include the brackets, the bracketed material or the underscoring.*

SECTION 16. If any provision of this Act, or the application of any provision of the Act to any person or circumstance, is held invalid, the application of such provision to other persons or circumstances, and the remainder of this Act, shall not be affected thereby.

SECTION 17. This Act shall take effect on July 1, 1972.

(Approved May 30, 1972.)

*Edited accordingly.