ACT 214

H.B. NO. 1818

A Bill for an Act Relating to Prescription Drugs.

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

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

"**§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 U.S.C. 301 et seq.);

(3) "Food" means (A) articles used for food or drink by humans, dogs, or cats, (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) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; (C) articles (other than food) intended to affect the structure or any function of the body of humans 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 identification 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 humans or animals; or (B) to affect the structure or any function of the body of humans 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., secs. 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. 451 et seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 601 et seq.);

(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:

(A) Any meat or meat products or poultry or poultry products, except as these products are sold at retail in stores and restaurants in

normal retail quantities, provided that any labeling requirements imposed under authority of this part shall comply with those established by the Secretary of Agriculture, United States Department of Agriculture;

(B) Any tobacco or tobacco products;

(C) 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 U.S.C. 151-158), commonly known as the Virus-Serum-Toxin Act;

(D) Any drug subject to the provisions of section 503(b)(1) or 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1) and 356);

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

(F) Any commodity subject to the provisions of the Federal Seed Act (7 U.S.C. 1551-1611).

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

(14) ''Out-of-state practitioner'' includes a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, veterinarian, or any other person who is authorized to prescribe drugs to patients under the applicable laws of any state of the United States;

(15) ''Pharmacist'' means a person licensed under chapter 461 to practice in a pharmacy;

(16) ''Practitioner'' means an individual licensed by the State to prescribe prescription drugs within the scope of the person's practice; and

(17) ''Pharmacy intern'' means a student or graduate of a school or college of pharmacy issued a permit by the board of pharmacy to work under the immediate supervision of a pharmacist.]

For the purposes of this chapter:

''Color additive'' means a material which:

(1) 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

(2) 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;

The term ''color'' includes black, white, and intermediate grays.

Nothing in this definition 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.

''Consumer commodity'' means any food, drug, cosmetic, or device as those terms are defined by this part or the Federal Act. The term shall not include:

(1) Any meat or meat products or poultry or poultry products, except as these products are sold at retail in stores and restaurants in normal retail quantities; provided that any labeling requirements imposed under

authority of this part shall comply with those established by the Secretary of Agriculture, United States Department of Agriculture;

(2) Any tobacco or tobacco products;

(3) 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 U.S.C. §§151-158), commonly known as the Virus-Serum-Toxin Act;

(4) Any drug subject to section 503(b)(1) or 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§353(b)(1) and 356);

(5) Any beverage subject to or complying with packaging and labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. §§201-219a); or

(6) Any commodity subject to the Federal Seed Act (7 U.S.C. §§1551-1611).

"Cosmetic" means:

(1) 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; or

(2) Articles intended for use as a component of any such articles, except that the term shall not include soap intended for cleansing purposes only.

"Department" means the department of health.

"Device", except when used (e.g., as an identification 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:

(1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or

(2) To affect the structure or any function of the body of humans or animals.

"Director" means the director of health.

"Drug" means:

(1) Articles recognized in the official United States Pharmacopoeia, official United States Pharmacopoeia Dispensing Information, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Articles (other than food) intended to affect the structure or any function of the body of humans or animals; or

(4) Articles intended for use as a component of any article specified in this definition above but not including devices or their components, parts, or accessories.

"Drug sample" means a unit of a prescription drug that is not to be sold and is distributed to promote the sale of the drug under requirements of Public Law No. 100-293.

"Federal Act" means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040; 21 U.S.C. §§301-395).

"Food" means:

(1) Articles used for food or drink by humans, dogs, or cats;

(2) Chewing gum; or

(3) Articles used for components of any such article.

"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:

(1) A pesticide chemical in or on a raw agricultural commodity;

(2) 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;

(3) A color additive; or

(4) 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. §§451-470), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. §§601-695).

"Good manufacturing practices for drugs" means requirements for the manufacture, repacking, production, storage, and dispensing of drug products as stated in 21 C.F.R. Parts 207, 210, and 211.

"Official compendium" means the official United States Pharmacopoeia, official United States Pharmacopoeia Dispensing Information, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

"Out-of-state practitioner" means a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe drugs to patients under the applicable laws of any state of the United States except the State of Hawaii, or a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe drugs under the applicable laws of Hawaii, but practicing in a state other than Hawaii.

"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 amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

"Pharmacist" means a person licensed under chapter 461 to practice in a pharmacy.

"Pharmacy intern" means a student or graduate of a school or college of pharmacy issued a permit by the board of pharmacy to work under the immediate supervision of a pharmacist.

"Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person's practice.

"Prescription" means an order or formula issued by a practitioner for the compounding or dispensing of drugs, or an order or formula issued by an out-of-state practitioner in compliance with section 328-17.6.

"Prescription drug" means any drug required by federal or state statutes, regulations, or rules to be dispensed only by a prescription, including finished

dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Act.

"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."

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, 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 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 [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 subparagraph (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) Except as provided in part VI, 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] 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 [(1) are]:

(A) Are engaged in the packaging or labeling of such commodities[, or (2) prescribe]; or[1]

(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. The provisions of 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 [practitioner thereof;] 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."

SECTION 3. Section 328-15, Hawaii Revised Statutes, is amended to read as follows:

"**§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)(C);] provided that under [clause (B) of] this [paragraph] subparagraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with [regulations prescribed] rules adopted by the director [of health]. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count shall not be required for 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 U.S.C. §§151-158), commonly known as the Virus-Serum-Toxin Act.

(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 a person and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine, codeine, heroin, [marihuana,] marijuana, 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,] habit forming, by [regulations issued] rules adopted 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.''] habit forming.''

(5) (A) If it is a drug unless [(1) its]:

(i) 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 these specifically named in this paragraph, shall apply only to prescription drugs; and [(2) for]

(ii) 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] rules adopted 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, in the United States Pharmacopoeia Dispensing Information, 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] subparagraph (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] adopt rules 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] packaging 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 Pharmacopoeia 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] rules adopted by the director or regulations issued under the Federal Act require as necessary for the protection of public health. No such [regulation] rule 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] paragraph, the term "antibiotic drug" means any drug intended for use by a person containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms 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] rules adopted 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] rules adopted by the director.

(17) If it has met or exceeded the expiration date established by the manufacturer or principal labeler."

SECTION 4. Section 328-16, Hawaii Revised Statutes, is amended by amending subsections (c) and (d) to read as follows:

"(c) For the purposes of this section, a "prescription drug" is a drug intended for use by a person which:

(1) Is a [habit-forming] habit forming drug to which section 328-15(4) applies;

(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].

(d) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner [licensed by law to administer the drug] shall be exempt from the

requirements of section 328-15 (except paragraphs (1), (9), (11), and (12), and the packaging requirements of paragraphs (7) and (8)), if the drug bears a label containing: [the]

(1) The name and address of the [dispenser, the] pharmacy;
(2) The serial number and date of the prescription or of its filling[, the];
(3) The name of the [prescriber] practitioner; and[, if]
(4) If stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsections (a) and (b) of this section."

SECTION 5. Section 328-17.7, Hawaii Revised Statutes, is amended to read as follows:

"**[[]§328-17.7[]] Record of prescriptions.** Every [licensed physician] practitioner or pharmacist who compounds, sells, or delivers any prescription containing any poisonous drug, or substance deleterious to human life, to be used as medicine, shall enter upon the [physician's] practitioner's or pharmacist's books the prescription written out in full, with the date thereof, with the [physician's] practitioner's or pharmacist's own name appended thereto, or the name of the [physician] practitioner who prescribed the same, and the person to whom the same was delivered. No prescription shall be compounded, sold, or delivered unless the name of the person compounding, selling, or delivering the same, or the name of the [physician] practitioner prescribing the same, is appended to the prescription in full, and every prescription shall be preserved for a period of not less than five years. The books and prescriptions shall be subject at all times to the inspection of the director of health or the director's agent."

SECTION 6. Section 328-92, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) In filling initial or original prescriptions, the pharmacist shall not substitute an equivalent drug product if the practitioner, and only the practitioner, handwrites "do not substitute" on the written prescription. The pharmacist shall not substitute an equivalent drug product if a prescription is ordered orally and the practitioner or authorized employee of the practitioner orally orders "do not substitute".

The pharmacist shall note the practitioner's instructions on the prescription record required to be maintained under section 328-17.7.

In refilling prior written prescriptions, the pharmacist shall not substitute an equivalent drug product if the oral prescription is a refill of a prior written prescription for which selection of an equivalent drug product was not permitted; provided that if the prior written prescription permitted the selection of an equivalent drug product, substitution shall be permitted. The pharmacist, however, shall not substitute an equivalent drug product if a refill of a prescription is ordered orally and the practitioner or authorized employee of the practitioner orally orders "do not substitute".

The designation of "do not substitute" and the [physician's] practitioner's signature shall not be preprinted or stamped on the prescription."

SECTION 7. Section 328-96, Hawaii Revised Statutes, is amended by amending subsection (d) to read as follows:

"(d) The department of health shall provide for distribution of the formulary, revisions, and supplements to all [pharmacists and practitioners licensed and practicing in this] pharmacies in the State and to any other [appropriate] interested individuals. The department of health may establish fees to be charged to persons who receive the formulary, revisions, and supplements. The amounts of the fees charged for the formulary, revisions, and supplements shall be approximately the same as the costs of producing and distributing the formulary, revisions, and supplements."

SECTION 8. Section 461-1, Hawaii Revised Statutes, is amended by amending the definitions of "practitioner" and "prescription" to read as follows:

""'Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person's practice.

"Prescription" means an order or formula issued by a practitioner licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice, for the compounding or dispensing of drugs or an order or formula issued by an out-of-state practitioner in compliance with chapter 328."

SECTION 9. Section 461-19, Hawaii Revised Statutes, is amended to read as follows:

"§461-19 Application of law. This chapter shall not apply to any practitioner legally licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice when the practitioner is handling drugs in the course of the practitioner's professional duties or prohibit the practitioner from personally supplying the practitioner's own patients with such prescription drugs if the prescription drugs fall within the practitioner's scope of authorized practice."

SECTION 10. Section 328-91, Hawaii Revised Statutes, is amended as follows:

1. By repealing the definition of "pharmacist".

["'"Pharmacist" means a person licensed under chapter 461 to practice in a pharmacy."]

2. By repealing the definition of "practitioner".

["'"Practitioner" means an individual licensed by the State to prescribe prescription drugs within the scope of the person's practice."]

SECTION 11. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 12. This Act shall take effect upon its approval.

(Approved June 16, 1997.)

Note

1. Should be underscored.