ACT 152 H. B. 358.

A Bill for an Act Relating to the Hawaii Food, Drug and Cosmetic Act; Amending Chapter 51, Revised Laws of Hawaii 1955.

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

SECTION 1. Section 51-1, Revised Laws of Hawaii 1955, is amended by adding thereto the following new paragraphs:

"(i) '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;

"(j) '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;

"(k) '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

such 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 such term does not include: (1) a pesticide chemical in or on a raw agricultural commodity; or (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; or (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 and the following), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following),

"(l)(1) 'Color additive' means a material which—(A) 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 (B) 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 such term does not include any material which has been or hereafter is exempted under the Federal Act. (2) The term 'color' includes black, white and intermediate grays. (3) Nothing in clause (1) of section 51-1(1) 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."

SECTION 2. Section 51-4(b), Revised Laws of Hawaii 1955, is amended to read as follows:

"(b) 'New drug' means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

SECTION 3. Section 51-6, Revised Laws of Hawaii 1955, is amended:

(a) by amending paragraph (i) to read:

"(i) 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 such act is done while such article is held for sale and results in such article being adulterated or misbranded;"

(b) by amending paragraph (j) to read:

"(j) 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 the provisions of this Act or of the Federal Act;"

(c) by amending paragraph (m) to read:

"(m) 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 such drug who makes written request for information as to such 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 Act."

(d) by adding thereto the following new paragraphs:

"(n)(1) 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 (2) 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 subsection (1) hereof; or (3) 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;

"(o) 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."

SECTION 4. Section 51-9, Revised Laws of Hawaii 1955, is amended to read as follows:

"51-9. Foods to be deemed adulterated when. A food shall be deemed to be adulterated: (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quality of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance, other than one which is (i) a pesticide chemical in or on a raw agricultural commodity, or (ii) a food additive, or (iii) a color additive, which is unsafe within the meaning of section 51-13 (a); or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of

section 408 (a) of the Federal Act as amended; or (C) if it is or it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Act as amended; provided that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 408 of the Federal Act, and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 51-13 and clause (C) of this paragraph (a), not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food when ready-to-eat, is not greater than the tolerance prescribed for the raw agricultural commodity; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or (5) if it is the product of a diseased animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or (6) if its container is composed, in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health;

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is;

(c) If it is confectionery and—

(1) has partially or completely embedded therein any nonnutritive object; provided, that this clause shall not apply in the case of any nonnutritive object if, in the judgment of the director as provided by regulations, promulgated under the provisions of this Act, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extract; or

(3) bears or contains any nonnutritive substance: provided, that this clause shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provisions of this Act: and provided further, that the director may, for the purpose of avoiding or re-

solving uncertainty as to the application of this clause, issue regulations under the provisions of this Act, allowing or prohibiting the use of particular nonnutritive substances;

(d) If it is or bears or contains any color additive which is unsafe within the meaning of the Federal Act."

SECTION 5. Section 51-10, Revised Laws of Hawaii 1955, is amended:

(a) by amending paragraph (c) to read as follows:

"(c) 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 51-8; or if it is an imitation of another food that is not subject to subsection (g) 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;"

(b) by adding thereto the following new paragraphs:

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

"(m) If it is a color additive unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act."

SECTION 6. Section 51-13, Revised Laws of Hawaii 1955, is amended to read as follows:

"51-13. 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 (2) (A) of section 51-9 (a) with respect to any food, section 51-14 (a) with respect to any drug or device, or section 51-17 (a) with respect to any cosmetic, unless there is in effect a regulation pursuant to subsection (b) of this section limiting the quantity of such substance, and the use or intended use of such substance conform to the terms prescribed by such regulation. While such regulation relating to such substance is in effect, a food, drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulation, be considered adulterated within the meaning of clause 1, section 51-9 (a), section 51-14 (a) or section 51-17 (a).

(b) The director, whenever public health or other considerations in the State so require, is authorized to adopt, amend, or repeal regulations whether or not in accordance with regulations promulgated under the Federal Act prescribing therein tolerances for any added poisonous or deleterious substances, for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including, but not limited to, zero tolerances, and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a

food additive or a color additive may be safely used and exemptions where such food additive or color additive is to be used solely for investigational or experimental purposes, upon his own motion or upon the petition of any interested party requesting that such a regulation be established, and it shall be incumbent upon such petitioner to establish by data submitted to the director that a necessity exists for such regulation, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the director to determine whether such regulation should be promulgated, the director may require additional data to be submitted and failure to comply with the request shall be sufficient grounds to deny the request. In adopting, amending or repealing regulations relating to such substances the director shall consider among other relevant factors, the following which the petitioner, if any, shall furnish: (1) the name and all pertinent information concerning such substance including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations and suggestions and including specimens of proposed labeling, all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect; (2) the probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance; (3) the probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet; (4) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data; (5) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) such substance in or on an article, (ii) any substance formed in or on such article because of the use of such substance, and (iii) the pure substance and all intermediates and impurities and; (6) facts supporting a contention that the proposed use of such substance will serve a useful purpose."

SECTION 7. Section 51-13.5, Revised Laws of Hawaii 1955, is repealed.

SECTION 8. Section 51-14 (a), Revised Laws of Hawaii 1955, is amended to read as follows:

"(a)(1) If it consists in whole or in part of any filthy, putrid or decomposed substance; or (2) (A) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, or (3) if it is

a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it is a drug that bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act or (B) it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the Federal Act."

SECTION 9. Section 51-15, Revised Laws of Hawaii 1955, is amended:

(a) by amending paragraph (b) to read as follows:

"(b) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under clause (2) of this paragraph (b) reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the director."

(b) by amending paragraph (d) to read as follows:

"(d) 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 Act, or by regulations issued pursuant to section 502 (d) of the Federal Act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit-forming.'"

(c) by amending paragraph (e) to read as follows:

"(e) (1) If it is a drug unless its label bears, to the exclusion of any other non-proprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name, as defined in subparagraph (2), 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, degitalis, 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; provided further, that to the extent that compliance with the requirements of clause (ii) of this subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the director.

(2) As used in this paragraph (e), the term 'established name,' with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508 of the Federal Act, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: provided further, that where clause (B) 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."

(d) by amending paragraph (f) to read as follows:

"(f) Unless its labeling bears (1) adequate directions for use; and (2) 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 (1) 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 such 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."

(e) by amending paragraph (g) to read as follows:

"(g) 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 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 provisions of 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 (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail."

(f) by amending paragraph (h) to read as follows:

"(h) 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 such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements."

(g) by amending paragraph (k) to read as follows:

"(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) 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 (2) such certificate or release is in effect with respect to such drug."

(h) by amending paragraph (1) to read as follows:

"(l) 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 (1) 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 (2) such certificate or release is in effect with respect to such 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)."

(i) by amending paragraph (m) to read as follows:

"(m) 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 such packaging and labeling requirements applicable to such color additive prescribed under the provisions of section 13(b)."

(j) by adding thereto the following new paragraphs:

"(n) 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 (1) the established name, as defined in section 51-15 (e) (2) of this Act, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502 (e) of the Federal Act, and (3) such other information in brief summary relating to side effects, contra-indications, and effectiveness as shall be required in regulations issued by the director;

"(o) 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;

"(p) 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 Act, 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 10. Chapter 51, Revised Laws of Hawaii 1955, is amended by adding thereto a new section to be numbered section 51-15.1 and to read as follows:

"**Section 51-15.1. Drugs limited to dispensing on prescription.** (a) A drug intended for use by man which—(A) is a habit-forming drug to which section 51-15 (d) applies; or (B) 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 such drug; or (C) is limited by an approved application under section 505 of the Federal Act or section 51-16 of this Act to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such 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 such 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 of health or its agents, or (iii) 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 (iv) its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such practitioner. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 51-15 (except paragraphs (a), (i), (k), and (1), and the packaging requirements of paragraphs (g) and (h)), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such 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 paragraph (a) of this section.

(c) The director, may, by regulation, remove drugs subject to section 51-15 (d) and section 51-16 from the requirements of paragraph (a) of this section when such requirements are not necessary for the protection of the

public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by regulations issued by the director, be removed from the requirements of paragraph (a) of this section.

(d) A drug which is subject to paragraph (a) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription', or 'Caution: State law prohibits dispensing without prescription'. A drug to which paragraph (a) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(e) Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marihuana as defined in the applicable Federal and State laws relating to narcotic drugs and marihuana."

SECTION 11. Section 51-16, Revised Laws of Hawaii 1955, is amended to read as follows:

"**51-16. 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 said approval has not been withdrawn under section 505 of the Federal Act, or (2) when not subject to the Federal Act, unless such 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 such drug, there has been filed with the director an application setting forth (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drugs; (E) such samples of such 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 such 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, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, 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) This section shall not apply—

(1) to a drug intended solely for investigational use by experts qualified

by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the director or pursuant to section 505 (i) or 507 (d) of the Federal Act; or

(2) to a drug sold in this State at any time prior to the enactment of this Act or introduced into interstate commerce at any time prior to the enactment of the Federal Act; or

(3) to any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. Title 42 Chapter 6A Sec. 262); or

(4) to any drug which is subject to section 51-15 (1) of this Act.

(e) The provisions of section 51-4(b) shall not apply to any drug which, on October 9, 1962 or on the date immediately preceding the enactment of this subsection, (1) was commercially sold or used in this State or in the United States, (2) was not a new drug as defined by section 51-4 (b) as then in force, and (3) was not covered by an effective application under section 16* of this Act or under section 505 of the Federal Act, when such drug is intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug."

SECTION 12. Section 51-17 (e), Revised Laws of Hawaii 1955, is amended to read as follows:

"(e) If it is not a hair dye and it is or bears or contains a color additive which is unsafe within the meaning of the Federal Act."

SECTION 13. Section 51-18, Revised Laws of Hawaii 1955, is amended by adding thereto a new paragraph (e) to read as follows:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of 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 51-17(a))."

SECTION 14. If any provision of this Act is declared unconstitutional or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and applicability thereof to other persons and circumstances shall not be affected thereby.

SECTION 15. This Act shall take effect upon its approval.

(Approved May 29, 1967.)

* So in original.