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CHAPTER 40
GUAM FOOD, DRUG AND COSMETIC ACT

NOTE: P.L. 15-96 amended and renumbered Subchapter W of Chapter VI of Title X, which appears here as Chapter 40 of this Title.

- § 40101. Title.
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§ 40101. Title.

This Act may be cited as the “*Guam Food, Drug and Cosmetic Act.*”

SOURCE: GC § 9720.

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NOTE: The terms *this Act* and *Subchapter* were used synonymously in the original version of P.L. 13-143, with Subchapter being changed to Chapter here.

§ 40102. Definitions.

For the purpose of this Act:

(a) The *effective date* means the date this Act shall be implemented.

(b) The *Director* means the Director of the Department of Public Health and Social Services.

(c) The term *person* includes individual, partnership, corporation and association.

(d) The term *food* means:

(1) Articles used for food or drink for man or other animals;

(2) Chewing gum; and

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

(e) The term *drug* means:

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

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

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

(4) Articles intended for use as a component of any article, specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.

(f) The term *counterfeit drug* means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

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(g) The term *device* (except when used in Paragraph (o) of this Section and in §§ 40103(k), 40110(f), 40115(c) and (o) and 40119(c) 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 man or other animals; or

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

(h) The term *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; and

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

(i) The term *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.

(j) The term *consumer commodity*, except as otherwise specifically provided by this Subsection, means any food, drug, device or cosmetic as these terms are defined by this Act or by the Federal Act. Such term does not include:

(1) Any tobacco or tobacco product;

(2) Any commodity subject to packaging or labeling requirements imposed under the Guam Purchasing and Labeling Law (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. 151-157), commonly known as the Virus-Serum Toxin Act;

(3) Any drug subject to the provisions of §40116(a) or (b), or §40115(k) of this Act, or §503(b) (1) or §506 of the Federal Act;

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

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

(k) The term *label* means a display of English language written or printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term *principal display panel* means that part of a label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.

(m) The term *container* does not include package liners.

(n) The term *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 wrapping 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.

(o) The term *labeling* means all labels and other English language written, printed or graphic matter:

(1) Upon an article or any of its containers or wrappers; or

(2) Accompanying such article.

(p) The term *advertisement* means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.

(q) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide,

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except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder or such other use as involves prolonged contact with the body.

(r) The term *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.

(s) The term *contaminated with filth* applies to any food, drug, device or cosmetic not securely protected from dust, dirt or bacteria, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(t) The provisions of this Act regarding the selling of food, drugs, devices or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale; and the sale, dispensing and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.

(u) The term *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.

(v) The term *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.

(w) The term *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

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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. 541 et. seq.) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 et. seq.).

(x) (1) The term *color additive* means a material which (a) is a dye, pigment or other substance made by a process of synthesis or similar artificer, 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) or 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 2 (x) 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

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physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

(y) The term *Federal Act* means the Drug and Cosmetic Act (Title 21 U.S.C. 301 et. seq.) and the Federal Fair Packaging and Labeling Act.

(z) The term *pull date* means the calendar date printed by the manufacturer on the package or wrapping which represents the date after which the manufacturer recommends that the product not be sold:

(aa) The term *pack date* means the complete date (month in letters, day and year in numbers) printed by the manufacturer on the package, which represents the date the product has been produced and packaged.

SOURCE: GC § 9720.1, as amended by P.L. 14-17.

§ 40103. Prohibited Acts.

The following acts and the causing thereof within the territory of Guam are hereby prohibited:

(1) The manufacture, sale or 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, except that, in the case of a food for which the pull date has expired, it may be sold, provided that a sign or notice clearly expressing the fact that the pull date has expired is placed in a conspicuous place next to the items in such a manner as to clearly inform the consumer as to the affected commodities;

(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 distribution in commerce of a consumer commodity 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 Chapter and of regulations promulgated under authority of this Chapter; provided, however, 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:

(i) are engaged in the packaging or labeling of such commodities;

or

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- (ii) prescribe or specify by any means the manner in which such commodities are packaged or labeled;
- (5) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of §§40111 or 40117;
- (6) The dissemination of any false advertisement;
- (7) The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by §40123;
- (8) The giving of a guaranty or undertaking which is false;
- (9) The removal or disposal of a detained or embargoed article in violation of §40106;
- (10) The alteration, mutilation, destruction, obliteration or removal of the whole or 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;
- (11) Repackaging of food, drugs or cosmetics unless the repackaged product conforms to all labeling requirements set out in this Act;
- (12) 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 Chapter or of the Federal Act;
- (13) The using by any person to his own advantage, or revealing, other than to the Consumer Counsel or his authorized representative or to the Courts when relevant in any judicial proceeding of any information acquired under authority of this Chapter concerning any method or process which as a trade secret is entitled to protection;
- (14) The using, on the labeling of any drug or in any advertisement relating to such drug, or any representation or suggestion that an application with respect to such drug is effective under §40117, or that such drug complies with the provisions of such Section;
- (15) In the case of a prescription drug distributed or offered for sale in this Territory, 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

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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 labeling requirements imposed by or under other provisions of this Chapter;

(16) (i) 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

(ii) Selling, dispensing, disposing of or causing to be sold, dispensed of, 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 Paragraph (i) hereof; or

(iii) Making, selling or disposing of, causing to be made, sold or disposed of, keeping in possession, control or custody, or concealing any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another, or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug;

(17) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing of counterfeit drug;

(18) 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 the express permission in each case of the person ordering or prescribing.

SOURCE: GC § 9720.2.

§ 40104. Jurisdiction.

In addition to the remedies hereinafter provided, the Consumer Counsel or Director is hereby authorized to apply to the Superior Court for, and such Court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from

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violating any provision of §40103; irrespective of whether or not there exists an adequate remedy at law.

SOURCE: GC § 9720.3, as amended by P.L. 15-96.

§ 40105. Penalty.

(a) Any person who violates any of the provisions of §40103 shall be guilty of a misdemeanor.

(b) No person shall be subject to the penalties of Subsection (a) of this Section, for having violated Section 3(a) or (c) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the territory of Guam from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Act, designated this Act.

(c) No publisher, radio-broadcast licensee or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor or seller of the article to which a false advertisement relates, shall be liable under this Section for the dissemination of such false advertisement.

SOURCE: GC § 9720.4, as amended by P.L. 13-187.

NOTE: Subsection (b) appears here as in the original P.L. 13-143. See note to §40115.

§ 40106. Tags for Adulterated Articles; Violations.

(a) Whenever a duly authorized agent of the Director finds or has probable cause to believe that any food, drug, device, cosmetic or consumer commodity, as defined by this Act, is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this Act or is in violation of §§40111 or 40117 of this Act, he shall affix to such articles a tag or other appropriate marking giving notice that such 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 such article by sale or otherwise until permission for removal or disposal is given by an authorized agent of the Director or the Court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

(b) When an article is adulterated or misbranded or is in violation of §§40111 or 40117 of this Act it shall be liable to be proceeded against by petition of the judge of the Court for libel for condemnation of such article.

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When an authorized agent has found that an article which is embargoed or detained is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the Court finds that a sampled, detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the owner thereof under the supervision of an authorized agent, and all Court costs and fees, storage and other proper expenses shall be taxed against the owner of such article or his agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the Court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed has been executed, may be order direct that such article be delivered to the owner thereof for such labeling or processing under the supervision of an agent of the Director. The expense of such supervision shall be paid by the owner. The article shall be returned to the owner and the bond shall be discharged on the representation to the Court by the Director that the article is no longer in violation of this Act and that the expenses for such supervision have been paid.

(d) Whenever the Director or any of his authorized agents shall find in any room, building, vehicle of transportation or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable articles which are unsound or contain any filthy, decomposed or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the Director of his authorized agent shall forthwith condemn or destroy the same or in any other manner render the same unsalable as human food.

SOURCE: GC § 9720.5, as amended by P.L. 15-96.

§ 40107. Institution of Proceedings.

It shall be the duty of the Director to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Before the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Director or his designated agent, either orally or in writing, in person or by attorney, with regard to such contemplated proceeding.

SOURCE: GC § 9720.6.

§ 40108. Regulations under Federal Act Apply.

(a) Definitions and standards of identity, quality and fill of container and their amendments, now or hereafter adopted under authority of the Federal Act are the definitions and standards of identity, quality and fill of container in this Territory. However, when in his judgment such action will promote honesty and fair dealing in the interest of consumers, the Director may promulgate regulations establishing definitions and standards of identity, quality and fill of container for foods where no Federal regulations exist. In addition, the Director may promulgate amendments to any Federal or local regulations which set definitions and standards of identity, and may promulgate amendments to any Federal or local regulations which set standards of quality and fill of container for foods.

(b) Temporary permits now or hereafter granted for import of experimental packs of food varying from the requirements of Federal definitions and standards of identity are automatically effective in this Territory under the conditions provided in such permits. In addition, the Director may issue additional permits where they are necessary to the completion of conclusiveness of an otherwise adequate investigation and where the interests of consumers are safeguarded. Such permits are subject to the terms and conditions the Director may prescribe by regulation.

SOURCE: GC § 9720.7.

§ 40109. Adulterated Food.

A food shall be deemed to be adulterated:

(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 quantity of such substance in such food does not ordinarily render it injurious to health;

(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; (ii) a food additive; or (iii) a color additive, which is unsafe within the meaning of Section 14(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 the Federal Act; or

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(C) if it is or it bears or contains any food additive which is unsafe within the meaning of the Federal Act 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 by 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 §40113 and clause (C) of this Paragraph 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;

(3) If it consists in wholly or in part of a diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for food;

(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;

(5) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter, or of an animal that has been fed upon the uncooked offal from a slaughterhouse;

(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;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to §40113 of this Act or §409 of the Federal Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom;

(9) If any substance has been substituted wholly or in part therefor;

(10) If damage or inferiority has been concealed in any manner;

(11) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality of strength or make it appear better or of greater value than it is;

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(12) If it is confectionery, and (i) has partially or completely imbedded therein any non-nutritive object; provided, that this clause shall not apply in the case of any non-nutritive objective if in the judgment of the Director as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health; (ii) bears or contains any alcohol other than alcohol not in excess of one-half of the one percent (1/2 of 1%) by volume derived solely from the use of flavoring extracts; or (iii) bears or contains any non-nutritive substance; provided, that this clause shall apply to a safe non-nutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging or storing 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 provision of this Act; and provided further, that the Director may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular non-nutritive substances.

(13) If it is or bears or contains any color additive which is unsafe within the meaning of the Federal Act; or

(14) If the product has a *pull date* on the packaging which has expired.

SOURCE: GC § 9720.8.

NOTE: Subsection (2)(A)(iii) appears here as in the original P.L. 13-143. See Note to §40115.

§ 40110. Misbranded Food.

A food shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular;
- (2) If its labeling or packaging fails to conform with the requirements of §40120 of this Act;
- (3) If it is offered for sale under the name of another food;
- (4) If it is an imitation of another food unless its label bears in type of uniform size and prominence the word, *imitation*, and, immediately thereafter, the name of the food imitated;
- (5) If its container is so made, formed or filled as to be misleading;
- (6) If in package form, unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; (ii) an

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accurate statement of the net 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 (ii) of this Paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the Director;

(7) If any word, statement or other information required by or under authority of this Act 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;

(8) If it purports to be or is represented as food for which a definition and standard of identity has been prescribed by regulations as provided by §40118, unless (i) it conforms to such definition and standard, and (ii) its label bears the name of the food specified in the definition and standards, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food;

(9) If it purports to be or is represented as: (i) a food for which a standard of quality has been prescribed by regulations as provided by §40108, and its quality falls below such standard, unless its label bears, in such manner and form as regulations specify, a statement that it falls below such standard; or (ii) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by §40108, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(10) If it is not subject to the provisions of Paragraph (8) of this Section unless it bears labeling clearly giving (i) the common or usual name of the food, if any there be and (ii) in case it is fabricated from two or more ingredients, the common 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 (ii) of this Paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Director;

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

(12) If it bears or contains any artificial flavoring, 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 promulgated by the Director. The provisions of this Paragraph and Paragraphs (8) and (10) with respect to artificial coloring do not apply to butter, cheese or ice cream. The provisions of the paragraph with respect to chemical preservatives do not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil;

(13) If it is a raw agricultural commodity 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, however, 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;

(14) 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; or

(15) If it is a color additive unless its packaging and labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act.

(16) If any locally packaged and/or processed food bears no calendar date indicating the pack date" written in English and which is easily legible and visible to the consumer.

SOURCE: GC § 9720.9, as amended by P.L. 14-17.

§ 40111. Imports.

(a) The owner or consignee of each import shipment of any article subject to the provisions of this Chapter, shall furnish to the Director, at least seven (7) working days prior to importation, accurate information with

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respect to the identity, quantity and value, source and origin, ownership, location of the import shipment and any other pertinent information needed or required by regulation to be promulgated by the Director.

(b) The Director, Customs & Quarantine Agency, shall deliver to the Director, upon his request, samples of food, drugs, devices and cosmetics which are being imported or offered for import into Guam, giving notice thereof to the owner or consignee, who may appear before the Director and have the right to introduce testimony. The Director shall furnish to the Customs & Quarantine Agency a list of establishments registered in accordance with Subsection (i) of §510 of the Federal Act, and shall request that if any drugs manufactured, prepared, propagated, compounded or processed in an establishment not so registered are imported or offered for import into Guam, samples of such drugs be delivered to the Director with notice of such delivery to the owner or consignee, who may appear before the Director and have the right to introduce testimony. If it appears from the examination of such samples of food, drugs, devices and cosmetics, or otherwise that (1) such article has been manufactured, processed or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded or is in violation of §40117 of this Chapter, then such article shall be refused admission, except as provided in Subsection (c) of this Section. The Customs & Quarantine Agency shall cause the destruction of any such article refused admission unless such article is exported under regulations prescribed by the Customs & Quarantine Agency within ninety (90) days of the date of the notice such refusal or within such additional time as may be permitted pursuant to such regulations. This Paragraph shall not be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Guam Uniform Controlled Substances Act.

(c) Pending decision as to the admission of an article being imported or offered for import, the Customs & Quarantine Agency may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to the regulations of the Customs & Quarantine Agency. If it appears to the Director that an article included within the provisions of clause (3) of Subsection (a) of this Section can, by relabeling or other action, be brought into compliance with this Chapter or rendered other than a food, drug, device or cosmetic, final determination as to admission of such article may

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be deferred and, upon filling of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this Subsection, the Director may in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Director's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Public Health and Social Services designated by the Director or an officer or employee of the Department of Commerce, Customs and Quarantine designated by the Director of that Department.

(d) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the government of Guam) in connection with the destruction provided for in Subsection (b) of this Section and the supervision of the relabeling or other action authorized under the provisions of Subsection (c) of this Section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage or labor with respect to any article refused admission under Subsection (b) of this Section, shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignees.

SOURCE: GC § 9720.10.

NOTE: The Legislature has separated Customs & Quarantine from the Department of Commerce. See 5 GCA Chapter 73.

§ 40112. Exemptions from Labeling Requirement.

The Director shall promulgate regulations exempting from any labeling requirement of this Act 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 Act upon removal from such processing, labeling or repacking establishment. Regulations now or hereafter adopted under authority of the Federal Act relating to such exemptions are automatically effective in this Territory. However, the Director may promulgate additional regulations or amendments to existing regulations concerning exemptions.

SOURCE: GC § 9720.11.

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§ 40113. Unsafe Substances.

(a) Any added poisonous or deleterious substance, any 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) of §40109 with respect to any food, §40114 with respect to any drug or device or §40118 with respect to any cosmetic, unless there is in effect a regulation pursuant to §40122 of this Act or Subsection (b) of this Section limiting the quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulations relating to such substance are in effect, a food, drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations, be considered adulterated within the meaning of clause (1), §§40109, 40114 or 40118.

(b) The Director, whenever public health or other considerations in this Territory 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. It shall be incumbent upon such petitioner to establish by data submitted to the Director that a necessity exists for such regulations, 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

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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.

SOURCE: GC § 9720.12.

§ 40114. Adulterated Drugs.

A drug or device shall be deemed to be adulterated:

(1) If it consists in whole or in part of any filthy, putrid or decomposed substance;

(2) If it has been produced, prepared, packed or held under unsanitary conditions where by it may have been rendered injurious to health;

(3) 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;

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(4) If it is a drug and its container is composed, in whole or in part, or any poisonous or deleterious substance which may render the contents injurious to health;

(5) If it is a drug and it bears or contains for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act;

(6) If 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;

(7) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the Federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this Paragraph because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label. 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 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;

(8) If it is not subject to the provisions of Paragraph (b) of this Section and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess; or

(9) If it is a drug and any substance has been (i) mixed or packed therewith so as to reduce its quality or strength; or (ii) substituted wholly or in part therefor.

SOURCE: GC § 9705.13.

§ 40115. Misbranded Drugs.

A drug or device shall be deemed to be misbranded:

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(1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of §40120 of this Act;

(2) If in package form unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; and (ii) 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 §40102(i)(3) of this Act; provided, that under clause (ii) of this Paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the Consumer Counsel or issued under the Federal Act;

(3) If any word, statement or other information required by or under authority of this Act 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, bramble, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote or sulfonmethane, 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 §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*;

(5) If it is a drug, unless:

(A) 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 Paragraph (6) 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

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and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, aminopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucoside, 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

(B) 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; and provided that to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this Subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the Director, or under the Federal Act;

(6) As used in this Paragraph and Paragraph (5), the term "established name," with respect to a drug or ingredient thereof, means:

(A) the applicable official name designated pursuant to §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 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;

(7) Unless its labeling bears (i) adequate directions for use, and (ii) 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

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form, as are necessary for the protection of users; provided, that where any requirement of clause (i) 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 §502(f) of the Federal Act may also be exempt;

(8) 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 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 (5) as to the name by which the drug or its ingredients shall be designated, the requirements of Paragraph (e) shall prevail;

(9) If it has been found by the Director or under the Federal Act 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;

(10) If it is a drug and its container is so made, formed or filled as to be misleading (i) if it is an imitation of another drug; (ii) if it is offered for sale under the name of another drug;

(11) 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;

(12) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (i) it is from a batch with respect to which a certificate or release has been issued pursuant to §506 of the Federal Act, and (ii) such certificate or release is in effect with respect to such drug;

(13) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline,

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chloramphenicol, bacitracin or any other antibiotic drug, or any derivative thereof, unless (i) it is from a batch with respect to which a certificate or release has been issued pursuant to §507 of the Federal Act, and (ii) 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 §507(c) or (d) of the Federal Act. For the purpose of this Paragraph the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution (including, the chemically synthesized equivalent of any such substance);

(14) 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 §40113 or of the Federal Act;

(15) In the case of any prescription drug distributed or offered for sale in this Territory 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 (i) the established name, as defined in Section 16(c)(2) of this Act, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under §502(c) of the Federal Act, and (iii) such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations issued under the Federal Act;

(16) 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; or

(17) 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 or under the Federal Act.

SOURCE: GC § 9720.14.

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NOTE: The reference in Subsection (15)(i) of this Section to "Section 16(c)(2) of this Act" indicates that an earlier draft of the bill which became P.L. 13-143 was numbered differently, and that the numbering was not changed when Government Code section numbers were added. This may also explain the provisions of §§40105(b), 40116(a) and (c), and 40109(2)(A)(iii). Assuming that §40101 of this Chapter was Section 1 of the original bill, then the numbers referred to in the sections cited above would appear to correspond to numbers of sections in the Government Code as renumbered and included in this compilation, as follows:

Section 3(a) or (c)" as referred to in §40105(b) would be §40103(1) or (3), (note the subsection numbers have apparently been changed from alphabetical in the original bill to numerical in P.L. 13-143); "Section 14(a)" as referred to in §40109(2)(A)(iii) would be §40114(1); "Section 16(c)(2)" as referred to in this Section would be §40117(a)(B), (note that P.L. 13-143, and consequently this Chapter, is not consistent in numbering subsections either alphabetically or numerically, with the result that renumbering or relettering one section would require renumbering and relettering of all cross-references in each Section.

§ 40116. Habit-Forming Drugs; Toxic Drugs.

(a) A drug intended for use by man which:

(A) is a habit-forming drug to which §40115(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 §505 of the Federal Act or Section 18 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 which is reduced promptly to writing and filed by the pharmacist, 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. If any prescription for such drug does not indicate the times 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 the provisions of this Paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

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(b) 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 §40115, except Subsections (a)(i)(2) and (3), (k) and (l) and the packaging requirements of Subsections (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 drugs 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 §40115(d) and Section 18 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 requirement of Paragraph (a).

(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 local laws relating to narcotic drugs and marihuana.

SOURCE: GC § 9720.15.

NOTE: Reference to "Section 18" appear here as in P.L. 13-143. See NOTE to §744.

§ 40117. Sale of New Drugs.

(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 §505 of the Federal Act, or (2) when not subject to the Federal Act, unless such drug has

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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 (i) 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; (ii) a full list of the articles used as components of such drug; (iii) a full statement of the composition of such drug; (iv) a full description of the methods used in, and the facilities and controls used for the manufacturer, processing and packing of such drug; (v) such samples of such drug and of the articles used as components thereof as the Director may require; and (vi) 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 (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 manufacturer, 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) Vacant.

(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 pre-clinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

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(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 maintenances 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 drug, 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 human beings 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 human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this Subsection shall be construed to require any clinical investigator to submit directly to the Director reports on the investigational use of drugs; provided, that the regulations adopted under Section 505(i) of the Federal Act shall be the regulations in this Territory; provided further, that the Director may in his discretion promulgate regulations whether or not in accordance with regulations promulgated under the Federal Act.

(e)(1) In the case of any drug for which an approval of an application filed pursuant to this Section is in effect, the applicant 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 drug, as the Director may by general regulation or by order with respect to such application prescribe; provided, however, that regulations and orders issued under this Subsection and under Subsection (d) shall have due regard for the professional ethics of the

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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.

(2) 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 certify such records.

(f) The Director may, after affording an opportunity for public hearing and judicial appeal, 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.

(g) This Section shall not apply:

(1) to a drug sold in this Territory or introduced into interstate commerce at any time prior to the enactment of the Federal Act, if its labeling contained the same representations concerning the conditions of its use; or

(2) to any drug which is licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201 et. seq.), or under the Animal Virus-Serum-Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et. seq.); or

(3) to any drug which is subject to Section 16(1) of this Act.

SOURCE: GC § 9720.16.

NOTE: For explanation of Subsection (g)(3) see **NOTE** to §40115.

§ 40118. Adulterated Cosmetics.

A cosmetic shall be deemed to be adulterated:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual; provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously

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displayed thereon: "Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purpose of the paragraph and Paragraph (c) the term "hair dye" shall not include eyelash dyes or eyebrow dyes;

(2) If it consists in whole or in part of any filthy, putrid or decomposed substance;

(3) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health;

(4) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(5) If it is not a hair dye and it is, or it bears or contains a color additive which is unsafe within the meaning of §40113(a).

SOURCE: GC § 9720.17.

§ 40119. Misbranded Cosmetics.

A cosmetic shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular;

(2) If its labeling or packaging fails to conform with the requirements of §40120 of this Act;

(3) If in package form unless it bears a label containing (i) the name and place of business of the manufacturer, packer or distributor; and (ii) 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 (ii) of this Paragraph reasonable variations shall be permitted, and exemption as to small packages shall be established by regulations prescribed by the Director;

(4) If any word, statement or other information required by or under authority of this Act 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

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it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

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

(6) 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 §40118(a)(1); or

(7) 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, is exempted from the affirmative labeling requirements of this Act 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 is otherwise subject to all applicable provisions of this Act.

SOURCE: GC § 9720.18.

§ 40120. Labeling Requirements.

(a) All labels of consumer commodities, as defined by this Act, 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) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such

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representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(d) 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.

(e) Whenever the Director determines that regulations containing prohibitions or requirements other than those prescribed by Section 21(a) 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 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

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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 purpose of Paragraph (4) of Subsection (e), a package shall be deemed to be non functional slack-filled if it is filled of substantially less than its capacity for reasons other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such package; provided, that the Director may adopt any regulations promulgated pursuant to the Fair Packaging and Labeling Act which shall have the force and effect of law in this Territory.

(f) Any food, drug or consumer commodity for which the manufacturer or distributor has established or recommended a pull date or other date by which the food, drug or consumer commodity should be used shall:

(1) Have the *pull date*, "*best if used by date*, *expiration date* or *other date* by which the food, drug or consumer commodity should be used, clearly marked on the packaging or labeling. Color coding may be used if the meanings of the color codes are clearly and plainly displayed in close proximity to the consumer commodities. Any product with a date on it shall be clearly marked as to whether the date is the date of packaging, the pull date, the expiration date, or some other date.

(2) Any outdated food, drug or consumer commodity which is still fit for human consumption and which is more than two days outdated, may be sold, displayed in a retail store or offered for sale only if the item is still fit for human consumption and each package is clearly marked with the word "*Outdated* or "*Expired Merchandise* or such other words of similar meaning as may be approved by regulations promulgated by the Director of the Department of Public Health.

(3) Notwithstanding any provision of law, all fresh or frozen packaged meat, fresh eggs, bread, fresh milk and fresh daily products and ice cream, and such other food, drug and consumer commodity designated by the Director of the Department of Public Health and Social Services shall have a clearly designated expiration date on each package offered for retail sale. Notwithstanding any other provision of law, in lieu of stamping any required labels whatsoever on individual eggs, such information may instead be stamped on each egg carton if

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the eggs are packed in individual cartons of twelve (12) eggs or less as required by 5 GCA Chapter 66, the *Chicken Egg Regulation*. (g) Any dented or damaged package or can of consumer products shall clearly be marked "*Damaged*."

(h) Any fresh or frozen meat or poultry products which have had water added shall be clearly labeled "*Water added*." Any meat products which have been previously given a United States Department of Agriculture grade or category shall have the grade or category clearly marked on each package of meat offered for sale, whether or not later repackaged.

(i) It shall be unlawful to sell any rusty canned goods or goods with rusty metal lids, unless the rust can be removed by rubbing with a cotton cloth.

(j) It shall be a misdemeanor for any person to sell or offer for sale any food, drug or consumer commodity which is not clearly labeled and marked in English or Chamorro as herein provided for in this Chapter.

(k) In addition to criminal penalties for the violation of this Section, the Director of Public Health and Social Services shall, by rules and regulations to be established seize and destroy all food, drug, or consumer products which are displayed or offered for sale which are not properly marked or labeled in the English or Chamorro languages, and shall pursuant to regulations, impose civil penalties and fines not exceed Five Hundred Dollars (\$500) for each failure to properly label or mark products in English or Chamorro languages as provided by this Chapter, and may, pursuant to regulation, and close repeated offenders; shall

(l) In addition to any other penalties provided for by law, each violation of this Section shall be counted as at least one or more demerits as the conditions dictate, in determining demerit points in the issuance of sanitary permits or renewals thereof as provided for in 10 GCA Chapter 21. For purposes of this subsection, a minimum of one (1) demerit point must be given for each different inventory item found in violation of this Section, but exactly identical items found in violation may be counted as one violation.

(m) Any seller of food, drugs and consumer commodities found to have more than twenty (20) different products displayed or offered for sale which do not comply with the provisions of this Section shall be immediately closed in the same manner as an unsanitary establishment pursuant to the provisions of 10 GCA Chapter 21.

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(n) The Director of the Department of Public Health and Social Services shall promulgate rules and regulations to implement this Section pursuant to the Administrative Adjudication Act.

SOURCE: GC § 9720.19. Subsection (f) - (n) were added to §40120 by P.L. 19-41:1. Subsection (f)(3) amended by P.L. 28-33:4.

NOTE: The reference in Subsection (e) to "Section 21(a)" appears to be a reference to the Subsection (a) of this Section, which tends to confirm the explanation of these anomalous references presented in the note to §40115.

§ 40121. Advertising.

(a) An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this Act the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone diseases, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis, media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia or venereal disease shall also be deemed to be false, except that no advertisement not in violation of Subsection if it is disseminated only to members of the medical, dental or veterinary professions, or appears only in the scientific periodicals of these professions or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly in the sale of such drugs or devices; provided, that whenever the Director determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Director shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Director may deem necessary in the interests of public health; provided, that this Subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

SOURCE: GC § 9720.20.

§ 40122. Regulations.

(a) The authority to promulgate regulations for the efficient enforcement of this Act is hereby vested in the Director. The Director is hereby

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authorized to make the regulations promulgated under this Act conform, insofar as practicable, with those promulgated under the Federal Act.

(b) Hearings authorized or required by this Act shall be conducted by the Director or such officer, agent or employee as the Director may designate for the purpose.

(c) All pesticide chemical regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the pesticide chemical regulations in this Territory.

(d) All food additive regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the food additive regulations in this Territory.

(e) All color additive regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the color additive regulations in this Territory.

(f) All special dietary use regulations and their amendments now or hereafter adopted under authority of the Federal Food, Drug and Cosmetic Act are the special dietary use regulations in this Territory.

(g) All regulations and their amendments now or hereafter adopted under the Fair Packaging and Labeling Act shall be the regulations in this Territory. However, the Director may, if he finds it necessary in the interest of consumers, prescribe packaging and labeling regulations for consumer commodities, whether or not in accordance with regulations promulgated under the Federal Act; provided, that no such regulations shall be promulgated which are contrary to the labeling requirements for the quantity of contents required pursuant to Section 4 of the Fair Packaging and Labeling Act and the regulations promulgated thereunder.

(h) A Federal regulation automatically adopted pursuant to this Act takes effect in this Territory on the date it becomes effective as a Federal regulation. The Director shall publish all other proposed regulations in a newspaper of general daily circulation. A person who may be adversely affected by a regulation may, within thirty (30) days after publication of any other regulation, file with the Director in writing objections and a request for a hearing. The timely filing of substantial objections to a Federal regulation automatically adopted stays the effect of the regulation. If no substantial objections are received and no hearings are requested within 30

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(thirty) days after publication of a proposed regulation, it shall take effect on a date set by the Director. The effective date shall be at least sixty (60) days after the time for filing objections has expired. If timely substantial objections are made to a Federal regulation within thirty (30) days after it is automatically adopted or to a proposed regulation within thirty (30) days after it is published, the Director after notice, shall conduct a public hearing to receive evidence on the issues raised by the objections.

Any interested person or his representative may be heard. The Director shall act upon objections by order and shall mail the order to objectors by certified mail as soon after the hearing as practicable. The order shall be based on substantial evidence in the record of the hearing. If the order concerns a Federal regulation, it may reinstate, rescind or modify it. If the order concerns a proposed regulation, it may withdraw it or set an effective date for the regulation as published or as modified by the order. The effective date shall be at least sixty (60) days after publication of the order.

SOURCE: GC § 9720.21.

§ 40123. Inspections.

(a) For purposes of enforcement of this Act, the Director or any of his authorized agents, are authorized upon presenting appropriate credentials to the owner, operator or agent in charge:

(1) to enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed or 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; and

(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, and to obtain samples necessary to the enforcement of this Act. In the case of any factory, warehouse, establishment or consulting laboratory in which prescription drugs are manufactured, processed, packed or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act or which may not be manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this Act, have been or are being

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manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to the qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to Section 505(i) or (j) or Section 507(d) and (g) of the Federal Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to Section 505(j) of the Federal Act). Such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this Subsection shall not apply to:

(i) pharmacies which maintain establishments in conformance with local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(ii) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice;

(iii) persons who manufacture, prepare, propagate, compound or process drugs solely for use in research, teaching or chemical analysis and not for sale;

(iv) such other classes of persons as the Director may by regulation exempt from the application of this Section upon a finding that inspection as applied to such classes of persons in accordance with this Section is not necessary for the protection of the public health; and

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(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 cosmetics, 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 Act by reason of their receipt, carriage, holding or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator or agent in charge a report in writing setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid or decomposed substance or (2) has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Director.

(c) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises, he shall give to the owner, operator or agent in charge a receipt describing the samples obtained.

(d) When in the course of any such inspection of a factory or other establishment where food is manufactured, processed or packed, the officer or employee making the inspection obtains a sample of any such food and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid or decomposed substance or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator or agent in charge.

SOURCE: GC § 9720.22.

§ 40124. Report of Minor Violations.

Nothing in this Subchapter shall be construed as requiring the Director to report for the institution of proceedings under this Chapter, minor

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violations of this Chapter, whenever the Director believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

SOURCE: GC § 9720.23.

§ 40125. Emergency Permit Control.

(a) Whenever the Director finds after investigation that the distribution in the territory of Guam of any class of food may, by reason of contamination with microorganism during manufacture, processing or packing thereof in any locality, be injurious to health and that such injurious nature cannot be adequately determined after such articles have entered commerce, he then, and in such case only, shall promulgate regulations providing for the issuance to manufacturers, processors or packers of such class of food in such locality of permits to which shall be attached such conditions governing the manufacture, processing or packing, or packing of such class of food, for such temporary period of time as may be necessary to protect the public health; and after the effective date of such regulations and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed or packed by any such manufacturer, processor or packer unless such manufacturer, processor or packer holds a permit issued by the Director as provided by such regulations.

(b) The Director is authorized to suspend immediately upon notice any permit issued under authority of this Section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for reinstatement of such permit and the Director shall immediately after prompt hearing and inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Director shall have access to any factory or establishment, the operator of which holds a permit from the Director for the purpose of ascertaining whether or not the conditions of the permit are being complied with and denial of access for such inspection shall be grounds for suspension of the permit until access is freely given by the operator.

SOURCE: GC § 9720.24.

§ 40126. Reports of Judgment and Decrees.

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(a) The Director shall cause to be published from time to time reports summarizing all judgments, decrees and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Director shall also cause to be disseminated such information regarding food, drugs, devices and cosmetics as the Director deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this Section shall be construed to prohibit the Director from collecting, reporting and illustrating the results of the investigations of the Director.

SOURCE: GC § 9720.25.

§ 40127. Severability.

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

SOURCE: GC § 9720.26.

§ 40128. Effective Date.

The effective date of this legislation shall be one hundred eighty (180) days from the passage of this Act. Monthly reports of inspection, investigation and enforcement of this Act shall be made in a public newspaper of wide general circulation thereafter.

SOURCE: GC § 9720.27.

§ 40129. Authorization.

There is hereby authorized to be appropriated the sum of One Hundred One Thousand Two Hundred and Forty Dollars (\$101,240) to the Department of Public Health and Social Services, Bureau of Environmental Health and Consumer Protection for the implementation and administration of this Act.

SOURCE: GC § 9720.28.
