

TITLE 37
FOOD, DRUGS, AND OIL

CHAPTER 1
IDAHO FOOD, DRUG AND COSMETIC ACT

37-113. SHORT TITLE. This act may be cited as the Idaho Food, Drug and Cosmetic Act.

[37-113, added 1959, ch. 153, sec. 1, p. 351.]

37-114. DEFINITIONS. For the purpose of this act

(a) The term "board" means the state board of health and welfare and "director" means the director of the department of health and welfare.

(b) The term "person" includes individual, partnership, corporation, and association;

(c) 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;

(d) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, 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 or 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;

(e) The term "device" (except when used in paragraph (k) of this section and in section [sections] 37-115(g), 37-123(f), 37-127(b) and 37-130(c), Idaho Code) 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;

(f) 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;

(g) 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;

(h) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article, and a requirement made by or under authority of this 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 there be any, of the retail package of such article, or is easily legible through the outside container or wrapper;

(i) The term "immediate container" does not include package liners;

(j) The term "labeling" means all labels and other written, printed or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article;

(k) 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 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;

(l) 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;

(m) 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, 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;

(n) 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 of drugs, as safe 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 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;

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

(p) 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.

(q) The term "federal act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).

[37-114, added 1959, ch. 153, sec. 2, p. 351; am. 1974, ch. 23, sec. 14, p. 633.]

37-115. PROHIBITED ACTS. The following acts and the causing thereof within the state of Idaho are hereby prohibited:

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

(b) The adulteration or misbranding of any food, drug, device, or cosmetic;

(c) 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;

(d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 37-124 or 37-127;

(e) The dissemination of any false advertisement;

(f) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 37-133;

(g) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the state of Idaho from whom he received in good faith the food, drug, device, or cosmetic;

(h) The removal or disposal of a detained or embargoed article in violation of section 37-118;

(i) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this act;

(k) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 37-128, or that such drug complies with the provisions of such section.

[37-115, added 1959, ch. 153, sec. 3, p. 351.]

37-116. INJUNCTIONS AUTHORIZED. In addition to the remedies hereinafter provided the director is hereby authorized to apply to the district 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 violating any provision of section 37-115, Idaho Code, irrespective of whether or not there exists an adequate remedy at law.

[37-116, added 1959, ch. 153, sec. 4, p. 351; am. 1974, ch. 23, sec. 15, p. 633.]

37-117. VIOLATIONS -- PENALTY -- EXCEPTIONS.

(1) (a) Any person who intentionally adulterates a drug that is held for sale or distribution, or that is to be administered or dispensed, shall be guilty of a felony and shall, upon conviction thereof, be subject to imprisonment for not more than fifteen (15) years or a fine of not more than fifty thousand dollars (\$50,000), or both.

(b) Any health care provider who, with knowledge that a drug has been adulterated, permits that drug to be administered or dispensed to a person shall be guilty of a felony and shall, upon conviction thereof, be subject to imprisonment for not more than fifteen (15) years, or a fine of not more than fifty thousand dollars (\$50,000), or both. For the purposes of this subsection, the term "health care provider" shall be defined as any person licensed in this state to prescribe, dispense, conduct research with respect to, or administer drugs in the course of pro-

professional practice and any unlicensed person, who, as part of such person's employment or profession, provides health care services.

(c) The determination of whether or not a drug has been adulterated shall be made in accordance with the provisions of section 37-126, Idaho Code.

(2) Any person who violates any of the provisions of this act or of rules promulgated by the board of health and welfare thereunder or who interferes with the director of the department of health and welfare or the personnel of the department in the administration of this act shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than six (6) months or a fine of not more than five hundred dollars (\$500), or both such imprisonment and fine, but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than one (1) year, or a fine of not more than one thousand dollars (\$1000), or both such imprisonment and fine.

(3) No person shall be subject to the penalties of subsection (2) of this section, for having violated section 37-115 (a) or (c), Idaho Code, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the state of Idaho 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, designating this act.

(4) 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 by reason of the dissemination by him of such false advertisement, unless he has refused, on the request of the director to furnish him the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the state of Idaho who causes him to disseminate such advertisement.

[37-117, added 1959, ch. 153, sec. 5, p. 351; am. 1974, ch. 23, sec. 16, p. 633; am. 2002, ch. 231, sec. 1, p. 661.]

37-117A. REPORTING AND DISCLOSURE REQUIREMENTS FOR EMPLOYMENT RELATED ADULTERATION OR MISAPPROPRIATION OF CERTAIN DRUGS. (1) When the employment of a health care provider has been terminated, either voluntarily or involuntarily, for adulteration or misappropriation of controlled substances, as defined in chapter 27, title 37, Idaho Code, the employer shall, within thirty (30) days of the termination, furnish written notice of the termination, described herein as "notice of termination," to the health care provider's professional licensing board of the state of Idaho, which shall include a description of the controlled substance adulteration or misappropriation involved in the termination. An employer who in good faith provides such information shall not be held civilly liable for the disclosure or the consequences of providing the information. There is a rebuttable presumption that an employer is acting in good faith when the employer provides such information. The presumption of good faith is overcome only upon showing by clear and convincing evidence that the employer disclosed the information with actual malice or with deliberate intent to mislead. For the purposes of this section, "actual malice" means knowledge that the information was false or given with reckless disregard of whether the information was false. For the purposes of this section, the term "health care provider" means any person licensed by a professional licensing board of the state of Idaho

whose license permits the health care provider to dispense or administer controlled substances. For the purposes of this section, "employer" means a person or entity licensed under chapter 18, title 54, Idaho Code, or chapter 13, title 39, Idaho Code, who employs a health care provider or providers.

(2) A professional licensing board that receives a notice of termination from an employer pursuant to subsection (1) of this section shall maintain the notice of termination for the health care provider. The notice of termination shall be subject to disclosure in accordance with the provisions of subsection (3) of this section.

(3) Any prospective employer of a health care provider shall, before hiring such health care provider, request in writing that the health care provider's professional licensing board furnish the prospective employer any notice of termination maintained by the board with respect to the health care provider. The prospective employer shall maintain the confidentiality of such information and shall not disclose it to any other person or entity without the prior written approval of the health care provider or as required by law, court order or the rules of civil procedure. The professional licensing board shall require, as a condition of furnishing the notice of termination, that the prospective employer file a written request for the health care provider's notice of termination, stating under oath that the request for the notice of termination is made for a bona fide hiring purpose, that the request is made pursuant to the provisions of this section, and that the prospective employer will not disclose the information to any other person or entity without the prior written approval of the health care provider or as required by law, court order or rules of civil procedure. In the event that the prospective employer discloses the information in the notice of termination to any other person or entity in violation of the provisions of this section, and unless the disclosure is required by law, court order or the rules of civil procedure, the health care provider may pursue a civil cause of action against the prospective employer for a breach of the health care provider's right of privacy. Upon receipt of a request made in accordance with this section for a health care provider's notice of termination, the professional licensing board shall furnish the notice of termination to the prospective employer. The professional licensing board shall not be held liable for the correctness or completeness of the information contained in the notice of termination and shall include a disclaimer statement on all released information, attesting that the information has not been verified by the professional licensing board. An employer who obtains a notice of termination from the appropriate professional licensing board as provided in this section shall not be held civilly liable for hiring or contracting with a health care provider who the employer in good faith believes has been rehabilitated from drug abuse, absent the employer's gross negligence or reckless conduct.

(4) Notices of termination submitted hereunder shall be maintained and available to employers as set forth above for fifteen (15) years from the date of receipt by the professional licensing board.

[37-117A, added 2004, ch. 333, sec. 1, p. 993.]

37-118. TAGGING AND DETENTION OF ARTICLE OR PRODUCT SUSPECTED OF BEING ADULTERATED OR MISBRANDED -- EMBARGO AND CONDEMNATION UNDER CERTAIN CONDITIONS AND BY CERTAIN PROCEDURES. (a) Whenever a duly authorized agent of the director finds or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudu-

lent, within the meaning of this act, he shall affix to such article 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 such agent 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 detained or embargoed under subsection (a) of this section has been found by such agent to be adulterated, or misbranded, he shall petition the probate court or district court in the county in whose jurisdiction the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree be destroyed at the expense of the claimant thereof, under the supervision of such agent, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant 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 by order direct that such article be delivered to the claimant 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 claimant. Such bond shall be returned to the claimant of the article on representation to the court by the director that the article is no longer in violation of this act, and that the expenses of such supervision have been paid.

(d) Whenever the director or any of its authorized agents shall find in any room, building, vehicle of transportation or other structure, any meat, sea food, 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 or its authorized agent, shall forthwith condemn or destroy the same, or in any other manner render the same unsaleable as human food.

(e) Whenever the director or its duly authorized agent shall find, or have probable cause to believe, that any food, drug, device or cosmetic is offered or exposed for sale, or held in possession with intent to distribute or sell, or is intended for distribution or sale in violation of any provision of this act, whether it is in the custody of a common carrier or any other person, the director may affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, in violation of this act, and has been embargoed. Within seven (7) days after an embargo has been placed upon any article, the embargo shall be removed by the director or a summary proceeding for the confiscation of the article shall be instituted by the director. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the director or agent; or after summary proceedings have been instituted, without permission from the court. If the embargo shall be removed by the director or by the court, neither the director nor the state shall be held liable for damages

because of such embargo in the event that the court shall find that there was probable cause for the embargo.

(f) Such proceeding shall be by complaint, verified by affidavit, which may be made on information and belief in the name of the director or agent against the article to be confiscated.

(g) The complaint shall contain: (1) a particular description of the article, (2) the name of the place where the article is located, (3) the name of the person in whose possession or custody the article was found, if such name be known to the person making the complaint or can be ascertained by reasonable effort, and (4) a statement as to the manner in which the article is adulterated or misbranded or the characteristics which render its distribution or sale illegal.

(h) Upon the filing of the verified complaint, the court shall issue a warrant directed to the proper officer to seize and take in his possession the article described in the complaint and bring the same before the court who issued the warrant and to summon the person named in the warrant, and any other person who may be found in possession of the article, to appear at the time and place therein specified.

(i) Any such person shall be summoned by service of a copy of the warrant in the same manner as a summons issuing out of the court in which the warrant has been issued.

(j) The hearing upon the complaint shall be at the time and place specified in the warrant, which time shall not be less than five (5) days or more than fifteen (15) days from the date of issuing the warrant, but, if the execution and service of the warrant has been less than three (3) days before the return of the warrant, either party shall be entitled to a reasonable continuance. Upon the hearing the complaint may be amended.

(k) Any person who shall appear and claim the food, drug, device, or cosmetic seized under the warrant shall be required to file a claim in writing.

(l) If, upon the hearing, it shall appear that the article was offered or exposed for sale, or was in possession with intent to distribute or sell, or was intended for distribution or sale, in violation of any provision of this act, it shall be confiscated and disposed of by destruction or sale as the court may direct, but no such article shall be sold contrary to any provision of this act. The proceeds of any sale, less the legal costs and charges, shall be paid into the state treasury.

[37-118, added 1959, ch. 153, sec. 6, p. 351; am. 1974, ch. 23, sec. 17, p. 633.]

37-119. PROSECUTIONS OF VIOLATIONS -- RIGHT OF PARTY TO NOTICE AND PRESENTATION OF VIEWS PRIOR TO PROSECUTION. It shall be the duty of each county prosecuting attorney to whom the director or his agent reports any punishable violation of this act (including, but not limited to, rules and regulations) to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Before any violation of this act is reported to the county prosecuting attorney for 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.

[37-119, added 1959, ch. 153, sec. 7, p. 351; am. 1974, ch. 23, sec. 18, p. 633.]

37-120. REPORT OF MINOR VIOLATIONS. Nothing in this act shall be construed as requiring the director to report for the institution of proceedings under this act, minor violations of this act, whenever the director believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

[37-120, added 1959, ch. 153, sec. 8, p. 351; am. 1974, ch. 23, sec. 19, p. 633.]

37-121. PROMULGATION OF REASONABLE STANDARDS BY BOARD. Whenever in the judgment of the board such action will promote honesty and fair dealing in the interest of consumers, the board shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the federal act.

[37-121, added 1959, ch. 153, sec. 9, p. 351.]

37-122. FOOD DEEMED ADULTERATED. A food shall be deemed to be adulterated--(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 37-125; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or (5) if it is the product of a diseased animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

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

(c) If it is confectionery and it bears or contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per centum (.4%), harmless natural gum, and pectic; Provided, that this paragraph shall not apply to any confectionery by reason of its containing less than one-half

of one per centum (.5%) by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances.

(d) If it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the federal act.

[37-122, added 1959, ch. 153, sec. 10, p. 351.]

37-123. FOOD DEEMED MISBRANDED. A food shall be deemed to be misbranded--

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) 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.

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

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

(f) 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.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 37-121, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, in so far as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as--(1) A food for which a standard of quality has been prescribed by regulations as provided by section 37-121 and its quality falls below such standard unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (2) A food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 37-121, 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.

(i) If it is not subject to the provisions of paragraph (g) of this section, unless it bears labeling clearly giving (1) the common or usual name of the food, if any there be, and (2) 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 (2) of this paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the board.

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

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; Provided, that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

[37-123, added 1959, ch. 153, sec. 11, p. 351.]

37-124. CONTAMINATION OF FOOD WITH MICROORGANISMS -- PERMIT REGULATIONS -- ACCESS TO FACTORY. (a) Whenever the director finds after investigation that the distribution in Idaho of any class of food may, by reason of contamination with microorganisms 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 prescribe 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 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 the reinstatement of such permit, and the director shall, immediately after prompt hearing and an 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 ground for suspension of the permit until such access is freely given by the operator.

[37-124, added 1959, ch. 153, sec. 12, p. 351; am. 1974, ch. 23, sec. 20, p. 633.]

37-125. POISONOUS OR DELETERIOUS SUBSTANCE -- REGULATIONS AS TO USE. Any poisonous or deleterious substance added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of clause (2) of section 37-122(a); but when such substance is so required or cannot be so avoided, the board shall promulgate regulations limiting the quantity therein or thereon to such extent as the board finds

necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 37-122(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) section 37-122(a). In determining the quantity of such added substance to be tolerated in or on different articles of food, the board shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

[37-125, added 1959, ch. 153, sec. 13, p. 351.]

37-126. DRUGS OR DEVICES DEEMED ADULTERATED. A drug or device shall be deemed to be adulterated:

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under the authority of the federal act.

(b) 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, these 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. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of a practitioner prescribing the drug for the purpose of administering the drug to a patient.

(c) If it is not subject to the provisions of subsection (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. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of the practitioner prescribing the drug for the purpose of administering the drug to a patient.

(d) If it is a drug and any substance has been: (1) mixed or packed therewith so as to reduce its quality or strength; or (2) substituted wholly or in part therefor. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of the practitioner prescribing the drug for the purpose of administering the drug to a patient.

[37-126, added 1959, ch. 153, sec. 14, p. 351; am. 2002, ch. 231, sec. 2, p. 662.]

37-127. DRUGS OR DEVICES DEEMED MISBRANDED. A drug or device shall be deemed to be misbranded--(a) If its labeling is false or misleading in any particular.

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

(c) 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.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana [marijuana], morphine, opium, paraldehyde, peyete [peyote], or sulphonmethane, or any chemical derivative of such substance, which derivative has been by the board after investigation, found to be, and by regulations under this act, designated as habit forming, 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."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two (2) or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acotphenetidin, amidapyrine, anti-pyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis glucosines, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any substances, contained therein: Provided, that to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the

board shall promulgate regulations exempting such drug or device from such requirements.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that the method of packing may be modified with the consent of the board. 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.

(h) If it has been found by the board 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 board shall by regulations require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the board shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) 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.

(k) If it is a drug sold at retail and quantity of aminopyrine, barbituric acid, cinchophen, dinitrophenol, sulfanilamide or their derivatives, or any other drug which has been found by the board to be dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, and so designated by the board in a regulation adopted; unless it is sold on a written prescription signed by a member of the medical, osteopathic, chiropodial, dental, or veterinary profession who is licensed by law to administer such drug, and its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, osteopathic, chiropodial, dental, or veterinary profession.

(1) A drug sold on a written prescription signed by a member of the medical, osteopathic, chiropodial, dental, or veterinary profession (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of this section if--(1) such member of the medical, osteopathic, chiropodial, dental, or veterinary profession is licensed by law to administer such drug, and (2) such drug bears a label containing the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, osteopathic, chiropodial, dental, or veterinary profession.

[37-127, added 1959, ch. 153, sec. 15, p. 351.]

37-128. SALE OF NEW DRUGS -- REGULATIONS AND PROCEDURES. (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 become effective under

section 505 of the federal act, or (2) when not subject to the federal act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the director an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drugs and of the articles used as components thereof as the board may require; and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a) (2) shall become effective on the sixtieth (60th) day after the filing thereof, except that if the director finds after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply-- (1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs provided the drug is plainly labeled "For investigational use only"; or (2) to a drug sold in this state at any time prior to the enactment of this act or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) to any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U.S.C. 1934 ed. title 42, Chap. 4).

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

[37-128, added 1959, ch. 153, sec. 16, p. 351; am. 1974, ch. 23, sec. 21, p. 633.]

37-129. COSMETICS DEEMED ADULTERATED. A cosmetic shall be deemed to be adulterated--(a) 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 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 purposes of this paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

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

(c) 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 injurious to health.

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

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the federal act.

[37-129, added 1959, ch. 153, sec. 17, p. 351.]

37-130. COSMETICS DEEMED MISBRANDED. A cosmetic shall be deemed to be misbranded--(a) If its labeling is false or misleading in any particular.

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

(c) 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.

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

[37-130, added 1959, ch. 153, sec. 18, p. 351.]

37-131. FALSE 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 disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria [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, venereal disease, shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, osteopathic, chiropodial, 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 board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the board 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.

[37-131, added 1959, ch. 153, sec. 19, p. 351.]

37-132. REGULATIONS BY BOARD -- HEARINGS -- NOTICE. (a) The authority to promulgate regulations for the efficient enforcement of this act is

hereby vested in the board. The board is hereby authorized to make the regulations promulgated under this act conform, in so far as practicable with those promulgated under the federal act.

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

(c) Before promulgating any regulations contemplated by section 37-121; 37-123(j); 37-124; 37-127(d), (f), (g), (h), and (k), or 37-131(b), the board shall give appropriate notice of the proposal and of the time and place for a hearing. The regulation so promulgated shall become effective on a date fixed by the board (which date shall not be prior to 30 days after its promulgation). Such regulation may be amended or repealed in the same manner as is provided for its adoption, except that in the case of a regulation amending or repealing any such regulation the board, to such an extent as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.

[37-132, added 1959, ch. 153, sec. 20, p. 351.]

37-133. INSPECTION OF ESTABLISHMENTS -- EXAMINATION OF SPECIMENS -- REPORTS -- RECEIPT FOR SAMPLES. The director or his duly authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose: (1) of inspecting such factory, warehouse, establishment, or vehicle to determine if any of the provisions of this act are being violated, and (2) to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such sample. It shall be the duty of the director to make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this act is being violated.

(a) Upon the completion of any inspection of a factory, warehouse, or other establishment and prior to leaving the premises, the director or his duly authorized agent making the inspection shall give to the owner, operator, or agent in charge, a report in writing setting forth any condition or practice observed by him which in his judgment indicates that any food, drug, device, or cosmetic in the establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substances; or (2) has been prepared, packed, or held in unsanitary condition whereby it may have become contaminated with filth or whereby it may be rendered injurious to health.

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

(c) Whenever in the course of any such inspection of the factory, or other establishment where food is manufactured, processed, or packed, the director or his duly authorized agent making the inspection obtains a sample of any such food and if analysis is made of such sample for the purpose of determining whether such food consists in whole or part of any filthy, putrid or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be sent promptly to the owner, operator, or agent in charge.

[37-133, added 1959, ch. 153, sec. 21, p. 351; am. 1974, ch. 23, sec. 22, p. 633.]

37-134. PUBLICATION OF REPORTS BY DIRECTOR -- DISSEMINATION OF INFORMATION. (a) The director may 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 may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the board 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.

[37-134, added 1959, ch. 153, sec. 22, p. 351; am. 1974, ch. 23, sec. 23, p. 633.]

CHAPTER 2
ADULTERATION AND BRANDING -- [REPEALED]