AN ACT GENERALLY REVISING THE MONTANA FOOD, DRUG, AND COSMETIC ACT; REDEFINING THE TERM "BOTTLED WATER" TO CONFORM TO FEDERAL LAW; ELIMINATING REQUIREMENTS FOR WATER BOTTLERS UNDER THE ACT; DEFINING "DIETARY SUPPLEMENT" AND ADDING THE TERM TO THE DEFINITION OF "FOOD"; CLARIFYING THAT A FOOD SERVICE ESTABLISHMENT MEANS A PLACE THAT SERVES FOOD AT RETAIL TO THE PUBLIC; CLARIFYING THE DEFINITION OF "RETAIL MEAT ESTABLISHMENT"; ELIMINATING PERMIT REQUIREMENTS FOR MANUFACTURING, PROCESSING, OR PACKAGING FOOD BECAUSE THOSE REQUIREMENTS ARE PROVIDED FOR ELSEWHERE IN STATE LAW; AMENDING SECTIONS 50-31-103, 50-31-110, 50-31-208, 50-31-312, AND 50-31-501, MCA; AND REPEALING SECTIONS 50-31-205, 50-31-206, 50-31-207, 50-31-236, AND 50-31-238, MCA.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 50-31-103, MCA, is amended to read:

"50-31-103. Definitions. Unless the context requires otherwise, in this chapter, the following definitions apply:

(1) "Advertisement" means representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

~~(2) "Approved source" means water from a spring, artesian well, drilled well, municipal water supply, or other source that has been found by the department to be of a safe and sanitary quality.~~

~~(3) "Artesian water" means water that is forced from below the ground toward the surface through a well by natural underground pressure.~~

~~(4)~~(2) "Beef patty mix" means "hamburger" or "ground beef" to which have been added binders or extenders as those terms are understood by general custom and usage in the food industry.

~~(5)~~(3) "Bottled water" means ~~carbonated, demineralized, distilled, fluoridated, mineral, purified, sparkling, or other water that is from an approved source and that is disinfected and placed in a sealed container or package for human consumption~~ water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients, except that it may optionally contain safe and suitable antimicrobial agents.

~~(6) "Carbonated water" or "sparkling water" means water that contains carbon dioxide.~~

~~(7)~~(4) "Color" includes black, white, and intermediate grays.

~~(8)~~(5) (a) "Color additive" means a material that:

(i) is a dye, pigment, or other substance made by a process of synthesis or similar artifice or that is extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or

(ii) when added or applied to a food, drug, or cosmetic or to the human body is capable (alone or through reaction with another substance) of imparting color to the human body.

(b) The term does not include material that has been or is exempted under the federal act.

~~(9)~~(6) (a) "Consumer commodity", except as otherwise specifically provided by this subsection, means any food, drug, device, or cosmetic as those terms are defined by this chapter or by the federal act and regulations pursuant to the federal act.

(b) The term does not include:

~~(a)~~(i) any tobacco or tobacco product;

~~(b)~~(ii) a commodity subject to packaging or labeling requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, et seq.) 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 through 157), commonly known as the Virus-Serum-Toxin Act;

~~(c)~~(iii) a drug subject to 50-31-306(1)(m) or 50-31-307(2)(c) or section 503(b)(1) or 506 of the federal act (21 U.S.C. 353(b)(1) and 356);

~~(d)~~(iv) a beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 201, et seq.); or

~~(e)~~(v) a commodity subject to the Federal Seed Act (7 U.S.C. 1551 through 1610).

~~(10)~~(7) "Contaminated with filth" applies to a food, drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, ~~from~~ foreign or injurious contaminations.

~~(11)~~(8) "Cosmetic" means:

(a) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance;

(b) articles intended for use as a component of these articles, except that the term does not include soap.

~~(12)~~(9) "Counterfeit drug" means a drug, drug container, or drug label that, 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 who in fact manufactured, processed, packed, or distributed the drug and that falsely purports or is represented to be the product of or to have been packed or distributed by the other drug manufacturer, processor, packer, or distributor.

~~(13) "Demineralized water" means water that has been demineralized by distillation, deionization, reverse osmosis, or other methods and that contains not more than 10 parts per million total solids.~~

~~(14)~~(10) "Department" means the department of public health and human services provided for in 2-15-2201.

~~(15)~~(11) "Device" (except when used in 50-31-107(2), 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and 50-31-501(10)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

(a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(b) to affect the structure or function of the body of humans or other animals.

(12) "Dietary supplement" means a product, other than a tobacco product, that is intended to supplement the diet and that:

(a) is advertised only as a food supplement;

(b) bears or contains one or more of the following ingredients:

(i) a vitamin;

(ii) a mineral;

(iii) an herb or other botanical substance;

(iv) an amino acid;

(v) a dietary substance used to supplement the diet by increasing the total dietary intake or a concentrate, metabolite, constituent, extract, or combination of any ingredients described in subsections (13)(b)(i) through (13)(b)(iv);

(c) conforms to any additional provisions for the definition of dietary supplement found at 21 U.S.C. 321.

~~(16) "Distilled water" means purified water that has been vaporized and condensed.~~

~~(17) "Drinking water" means water that has undergone purification, distillation, demineralization, mineralization, activated carbon or particulate filtration, fluoridation, carbonation, or other similar process or has undergone minimum treatment consisting of ozonization or an acceptable disinfection process.~~

~~(18)~~(13) "Drug" means:

(a) articles recognized in the official United States Pharmacopoeia, official National Formulary, or a supplement to either of these;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(c) articles (other than food) intended to affect the structure or function of the body of humans or other animals;

(d) articles intended for use as components of any article specified in subsection ~~(18)(a)~~ (14)(a), ~~(18)(b)~~ (14)(b), or ~~(18)(c)~~ (14)(c) but does not include devices or their components, parts, or accessories.

~~(19)~~(14) "Federal act" means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301, et seq.).

~~(20) "Fluoridated water" means water that contains, naturally or by addition, fluoride ions in quantities of not less than 0.7 and not more than 1.4 milligrams per liter and that complies with the food and drug administration quality standards set forth in 21 CFR 103.35.~~

~~(21)~~(15) "Food" means:

(a) articles used for food or drink for humans or other animals;

(b) chewing gum; ~~and~~

(c) articles used for components of these articles; and

(d) dietary supplements.

~~(22)~~(16) (a) "Food additive" means a 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 food (including a substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and including a source of radiation intended for this use), if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

(b) The term does not include:

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

(ii) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or

transportation of a raw agricultural commodity;

(iii) a color additive;

(iv) a substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act, the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 603, et seq.).

~~(23)~~(17) "Food service establishment" means a restaurant, catering vehicle, vending machine, delicatessen, fast-food retailer, or any other place that serves food at retail to the public for consumption, either at or away from the point of service, and any facility operated by a governmental entity where food is served.

~~(24)~~(18) "Hamburger" or "ground beef" means ground fresh or frozen beef or a combination of both fresh and frozen beef, with or without the addition of suet, to which no water, binders, or extenders are added. There are four grades of hamburger or ground beef:

(a) "regular hamburger" or "regular ground beef" may have:

(i) a fat content no greater than the federal standard set forth in 9 CFR 319.15; and

(ii) a lean content of no less than 70%;

(b) "lean hamburger" or "lean ground beef" may have:

(i) a fat content no greater than 22%; and

(ii) a lean content of no less than 78%;

(c) "extra lean hamburger" or "extra lean ground beef" may have:

(i) a fat content no greater than 16%; and

(ii) a lean content of no less than 84%; and

(d) "super lean hamburger" or "super lean ground beef" may have:

(i) a fat content no greater than 12%; and

(ii) a lean content of no less than 88%.

~~(25)~~(19) "Honey" means the nectar and saccharine plant exudations, gathered, modified, and stored in the comb by honey bees, that are levorotatory and that contain not more than 25% of water, not more than 0.25% of ash, and not more than 8% sucrose.

~~(26)~~(20) "Label" means a display of written, printed, or graphic matter on the immediate container of an article. "Immediate container" does not include package liners.

~~(27)~~(21) "Labeling" means labels and other written, printed, or graphic matter:

(a) on an article or its containers or wrappers;

(b) accompanying the article.

~~(28)~~(22) "Menu" means a list presented to the patron that states the food items for sale in a food service establishment.

~~(29) "Mineral water" means water that contains more than 500 parts per million total dissolved mineral solids.~~

~~(30)~~(23) "New drug" means a drug, the composition of which is such that:

(a) it 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 its labeling; or

(b) the drug, as a result of investigations to determine its safety and effectiveness for use under the conditions prescribed, has become so recognized but that has not, other than in the investigations, been used to a material extent or for a material time under the conditions prescribed.

~~(31)~~(24) "Official compendium" means the official United States Pharmacopoeia, official National Formulary, or a supplement to either of these.

~~(32)~~(25) (a) "Package" means a container or wrapping in which a consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers.

(b) The term does not include:

(i) shipping containers or wrappings used solely for the transportation of a consumer commodity in bulk or in quantity to manufacturers, packers, or processors or to wholesale or retail distributors;

(ii) shipping containers or outer wrappings used by retailers to ship or deliver a commodity to retail customers if the containers and wrappings bear no printed matter pertaining to a particular commodity.

~~(33)~~(26) "Person" includes an individual, partnership, corporation, and association.

~~(34)~~(27) "Pesticide chemical" means a substance that alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, et seq.), as amended, and that is used in the production, storage, or transportation of raw agricultural commodities.

~~(35)~~(28) "Placard" means a nonpermanent sign used to display or describe food items for sale in a food service establishment or retail meat establishment.

~~(36)~~(29) "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.

~~(37)~~(30) "Processing" means cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, freezing, or otherwise manufacturing a food or changing the physical characteristics of a food~~;~~ and the enclosure of the food in a package.

~~(38) "Purified water" means water that is produced by distillation, deionization, reverse osmosis, or other method and that meets the definition of purified water in the 20th edition of the Pharmacopoeia of the United States of America, 1980.~~

~~(39)~~(31) "Raw agricultural commodity" means food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

~~(40)~~(32) "Retail meat establishment" means a commercial establishment at which meat or meat products are displayed for sale or provision to the public, with or without charge.

~~(41) "Spring water" means water that originates in an underground formation and flows naturally, without external force or vacuum, to a natural orifice in the surface of the earth.~~

~~(42)~~(33) "Synthetically compounded" means a product formulated by a process that chemically changes a material or substance extracted from naturally occurring plant, animal, or mineral sources, except for microbiological processes.

~~(43) "Water-bottling plant" means a facility in which bottled water is produced.~~

~~(44) "Well water" means water that:~~

~~(a) is taken from below the ground through a piping device or similar installed device using external force or vacuum;~~

~~(b) is not modified in its mineral content; and~~

~~(c) may have undergone minimum treatment consisting of ozonization or an acceptable disinfection process.~~"

Section 2. Section 50-31-110, MCA, is amended to read:

"50-31-110. Certain agricultural chemicals not color additives. Subsections ~~(7)~~ (5) and ~~(8)~~ (6) of 50-31-103 do not apply to a pesticide chemical, soil or plant nutrient, or other agricultural chemical that affects the color of produce of the soil, whether before or after harvest, solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil ~~and thereby affecting its color, whether before or after harvest~~."

Section 3. Section 50-31-208, MCA, is amended to read:

"50-31-208. Sale of hamburger and beef patty mix. (1) ~~No~~ A food service establishment or retail meat establishment may not use the terms "hamburger", "burger", or other similar term in any advertisement or menu to refer to any beef patty mix. A food service establishment or retail meat establishment selling or serving beef patty mix may refer to the product as "beef patty mix" or by any other term ~~which~~ that accurately informs the customer of the nature of the food product ~~which he is~~ being sold or served.

(2) If beef patty mix is sold or served in a food service establishment or retail meat establishment, a list of ingredients must appear on the menu or label~~,~~ or, if there is ~~no~~ not a menu or label, on a placard as follows:

(a) The term "beef patty mix" or any other term ~~which~~ that accurately informs the customer of the nature of the food product and its ingredients must be included.

(b) The ingredients must be listed in descending order of predominance by weight.

(c) ~~If there is no menu or label, the~~ The lettering on the placard must be at least 1 inch in height (72-point letters), in boldface, and in colors that contrast with the placard.

(d) The placard must be posted in a permanent place, conspicuous to the customer, in each room or area where food is served or sold at retail.

(3) If hamburger or ground beef is sold in a retail meat establishment, the grade of hamburger or ground beef, as ~~defined~~ enumerated in 50-31-103~~(24)~~(19), and the maximum fat and minimum lean content must appear on each displayed package or, if the product is not packaged for display, on a placard. If a placard is used, it must satisfy the requirements of subsections (2)(c) and (2)(d) ~~of this section~~. The provisions of this subsection do not apply to the service of prepared hamburger or ground beef at a food service establishment."

Section 4. Section 50-31-312, MCA, is amended to read:

"50-31-312. Exemptions from new drug application requirement. (1) Section 50-31-311 does not apply to:

(a) a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the department or pursuant to section 505(i) or 507(d) of the federal act (21 U.S.C. 355(i) or 357(d));

(b) a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act;

(c) any drug that is manufactured by an establishment licensed under 42 U.S.C. 262; or

(d) any drug that is subject to 50-31-306(1)(n).

(2) The provisions of 50-31-103~~(30)~~(24) do not apply to any drug, when the drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to the drug, that on October 9, 1962, or on the date immediately preceding July 1, 1967:

(a) was commercially sold or used in this state or in the United States;

(b) was not a new drug as defined by 50-31-103~~(30)~~(24) as then in force; and

(c) was not covered by an effective application under 50-31-311 or under section 505 of the federal act (21 U.S.C. 355)."

Section 5. Section 50-31-501, MCA, is amended to read:

"50-31-501. Prohibited acts. The following acts and the causing of the acts within the state of Montana are 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;

(3) the receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded and the delivery or proffered delivery ~~thereof~~ of any food, drug, device, or cosmetic for pay or otherwise;

(4) the sale, delivery for sale, holding for sale, or offering for sale of any article in violation of ~~50-31-205 or~~ 50-31-311;

(5) the dissemination of any false advertisement;

(6) the refusal to permit entry or inspection or to permit the taking of a sample, as authorized by 50-31-106;

(7) the giving of a guaranty or undertaking ~~which~~ if the 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~~ a person residing in the state of Montana and from whom the person received in good faith the food, drug, device, or cosmetic;

(8) the removal or disposal of a detained or embargoed article in violation of 50-31-509;

(9) the alteration, mutilation, destruction, obliteration, ~~or removal of the whole or any part of the labeling of or the doing of~~ or commission of any other act with respect to a food, drug, device, or cosmetic or the removal,

in whole or in part, of the labeling of a food, drug, device, or cosmetic if the act is done while the article is held for sale and results in the article being adulterated or misbranded;

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

(11) ~~the~~ using on the labeling of any drug or in any advertisement relating to the drug ~~of~~ any representation or suggestion that an application with respect to the drug is effective under 50-31-311 or that the drug complies with the provisions of 50-31-311;

(12) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor to maintain for transmittal or to transmit to any practitioner, licensed by applicable law to administer the drug and who makes written request for information as to the drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold or other printed matter as is approved under the federal act. This subsection does not exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(13) placing or causing to be placed upon any drug, ~~or~~ device, or container of a drug or device, with intent to defraud, the trade name, other identifying mark, or imprint of another or any likeness of the name, mark, or imprint;

(14) selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container of the drug or device with knowledge that the trade name, other identifying mark, or imprint of another or any likeness of any of the foregoing has been placed on the drug, device, or container in a manner prohibited by subsection (13);

(15) making, selling, disposing of, or causing to be made, sold, or disposed of or keeping in possession, control, or custody or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce ~~that~~ a trade name, other identifying mark, or imprint of another or any likeness of the name, mark, or imprint upon any drug, device, or container of the drug or device;

(16) the using by any person to the person's own advantage or revealing, other than to officers or employees of the department or the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of this chapter concerning any method or process that as a trade secret is entitled to protection;

(17) the distribution in commerce of a consumer commodity~~, as defined in this chapter,~~ if the commodity is contained in a package or if there is affixed to that commodity a label ~~which~~ that does not conform to the provisions of this chapter and of regulations promulgated under authority of this chapter. This prohibition does not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that the persons:

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

(b) prescribe or specify by any means the manner in which the commodities are packaged or labeled.

(18) the labeling or packaging of a food, drug, device, or cosmetic ~~which~~ that fails to conform with the requirements of this chapter."

Section 6. Repealer. Sections 50-31-205, 50-31-206, 50-31-207, 50-31-236, and 50-31-238, MCA, are repealed.

- END -

I hereby certify that the within bill,
HB 0050, originated in the House.

Chief Clerk of the House

Speaker of the House

Signed this _____ day
of _____, 2019.

President of the Senate

Signed this _____ day
of _____, 2019.

HOUSE BILL NO. 50

INTRODUCED BY HAINES

BY REQUEST OF THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

AN ACT GENERALLY REVISING THE MONTANA FOOD, DRUG, AND COSMETIC ACT; REDEFINING THE TERM "BOTTLED WATER" TO CONFORM TO FEDERAL LAW; ELIMINATING REQUIREMENTS FOR WATER BOTTLERS UNDER THE ACT; DEFINING "DIETARY SUPPLEMENT" AND ADDING THE TERM TO THE DEFINITION OF "FOOD"; CLARIFYING THAT A FOOD SERVICE ESTABLISHMENT MEANS A PLACE THAT SERVES FOOD AT RETAIL TO THE PUBLIC; CLARIFYING THE DEFINITION OF "RETAIL MEAT ESTABLISHMENT"; ELIMINATING PERMIT REQUIREMENTS FOR MANUFACTURING, PROCESSING, OR PACKAGING FOOD BECAUSE THOSE REQUIREMENTS ARE PROVIDED FOR ELSEWHERE IN STATE LAW; AMENDING SECTIONS 50-31-103, 50-31-110, 50-31-208, 50-31-312, AND 50-31-501, MCA; AND REPEALING SECTIONS 50-31-205, 50-31-206, 50-31-207, 50-31-236, AND 50-31-238, MCA.