

HOUSE BILL NO. 684
INTRODUCED BY GRINDE

IN THE HOUSE

FEBRUARY 14, 1989	INTRODUCED AND REFERRED TO COMMITTEE ON HUMAN SERVICES & AGING.
	FIRST READING.
FEBRUARY 18, 1989	COMMITTEE RECOMMEND BILL DO PASS AS AMENDED. REPORT ADOPTED.
FEBRUARY 20, 1989	PRINTING REPORT.
	SECOND READING, DO PASS.
FEBRUARY 21, 1989	ENGROSSING REPORT.
	THIRD READING, PASSED. AYES, 95; NOES, 4.
	TRANSMITTED TO SENATE.

IN THE SENATE

FEBRUARY 28, 1989	INTRODUCED AND REFERRED TO COMMITTEE ON PUBLIC HEALTH, WELFARE & SAFETY.
	FIRST READING.
MARCH 4, 1989	COMMITTEE RECOMMEND BILL BE CONCURRED IN. REPORT ADOPTED.
MARCH 6, 1989	SECOND READING, CONCURRED IN.
MARCH 8, 1989	THIRD READING, CONCURRED IN. AYES, 49; NOES, 1.
	RETURNED TO HOUSE.

MARCH 9, 1989

IN THE HOUSE

RECEIVED FROM SENATE.

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

1 HOUSE BILL NO. 684
2 INTRODUCED BY LARRY H. CRINOE
3
4 A BILL FOR AN ACT ENTITLED: "AN ACT TO AMEND THE MONTANA
5 FOOD, DRUG, AND COSMETIC ACT TO INCLUDE REGULATION OF
6 BOTTLED WATER; AND AMENDING SECTIONS 50-31-103, 50-31-110,
7 50-31-208, AND 50-31-312, MCA."
8
9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
10 **Section 1.** Section 50-31-103, MCA, is amended to read:
11 **"50-31-103. Definitions.** Unless the context requires
12 otherwise, in this chapter the following definitions apply:
13 (1) "Advertisement" means representations disseminated
14 in any manner or by any means, other than by labeling, for
15 the purpose of inducing or which are likely to induce,
16 directly or indirectly, the purchase of food, drugs,
17 devices, or cosmetics.
18 (2) "Approved source" means water from a spring,
19 artesian well, drilled well, municipal water supply, or
20 other source that has been found by the department to be of
21 a safe and sanitary quality.
22 (3) "Artesian water" means water that is forced from
23 below the ground to the surface through a well by natural
24 underground pressure.
25 (4) "Beef patty mix" means "hamburger" or "ground

1 beef" to which has have been added binders or extenders as
2 those terms are understood by general custom and usage in
3 the food industry.
4 (5) "Bottled water" means carbonated, demineralized,
5 distilled, fluoridated, mineral, purified, sparkling, or
6 other water that is from an approved source and placed in a
7 sealed container or package for human consumption.
8 (6) "Carbonated water" or "sparkling water" means water
9 that contains carbon dioxide.
10 (7) "Color" includes black, white, and intermediate
11 grays.
12 (8) (a) "Color additive" means a material which:
13 (i) is a dye, pigment, or other substance made by a
14 process of synthesis or similar artifice or extracted,
15 isolated, or otherwise derived, with or without intermediate
16 or final change of identity, from a vegetable, animal,
17 mineral, or other source; or
18 (ii) when added or applied to a food, drug, or cosmetic
19 or to the human body is capable (alone or through reaction
20 with other substance) of imparting color thereto.
21 (b) This term does not include material which has been
22 or hereafter is exempted under the federal act.
23 (9) "Consumer commodity", except as otherwise
24 specifically provided by this subsection, means any food,
25 drug, device, or cosmetic as those terms are defined by this

1 chapter or by the federal act and regulations pursuant
2 thereto. The term does not include:

3 (a) any tobacco or tobacco product;

4 (b) a commodity subject to packaging or labeling
5 requirements imposed under the Federal Insecticide,
6 Fungicide, and Rodenticide Act or the provisions of the
7 eighth paragraph under the heading "Bureau of Animal
8 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21
9 U.S.C. 151-157), commonly known as the virus, serum, and
10 toxin act;

11 (c) a drug subject to 50-31-306(1)(m) or
12 50-31-307(1)(c) or section 503(b)(1) or 506 of the federal
13 act;

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

17 (e) a commodity subject to the Federal Seed Act (7
18 U.S.C. 1551-1610).

19 {6}{10} "Contaminated with filth" applies to a food,
20 drug, device, or cosmetic not securely protected from dust,
21 dirt, and, as far as may be necessary by all reasonable
22 means, from foreign or injurious contaminations.

23 {7}{11} "Cosmetic" means:

24 (a) articles intended to be rubbed, poured, sprinkled,
25 sprayed on, introduced into, or otherwise applied to the

1 human body for cleansing, beautifying, promoting
2 attractiveness, or altering the appearance;

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

5 {8}{12} "Counterfeit drug" means a drug, drug container,
6 or drug label which, without authorization bears the
7 trademark, trade name, or other identifying mark, imprint,
8 or device or any likeness thereof of a drug manufacturer,
9 processor, packer, or distributor other than the person who
10 in fact manufactured, processed, packed, or distributed the
11 drug and which falsely purports or is represented to be the
12 product of or to have been packed or distributed by the
13 other drug manufacturer, processor, packer, or distributor.

14 {13} "Demineralized water" means water that has been
15 demineralized by distillation, deionization, reverse
16 osmosis, or other methods and contains not more than 10
17 parts per million total solids.

18 {9}{14} "Department" means the department of health and
19 environmental sciences provided for in Title 2, chapter 15,
20 part 21.

21 {10}{15} "Device" (except when used in 50-31-107(2),
22 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and
23 50-31-501(10)) means instruments, apparatus, and
24 contrivances, including their components, parts, and
25 accessories, intended:

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

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

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

(17) "Drinking water" means water that has undergone purification, distillation, demineralization, mineralization, fluoridation, carbonation, or other similar process or has undergone minimum treatment consisting of:

(a) activated carbon or particulate filtration; and

(b) ozonization or an equivalent disinfection process.

(18) "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 man or other animals;

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

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

(19) "Federal act" means the Federal Food, Drug, and Cosmetic Act, as amended (Title 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 complies with the food and drug administration quality standards set forth in 21 CFR 103.35.

(21) "Food" means:

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

(b) chewing gum; and

(c) articles used for components of these articles.

(22) (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

1 procedures or experience based on common use in food) to be
2 safe under the conditions of its intended use.

3 (b) This term does not include:

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

6 (ii) a pesticide chemical to the extent that it is
7 intended for use or is used in the production, storage, or
8 transportation of a raw agricultural commodity;

9 (iii) color additive;

10 (iv) substance used in accordance with a sanction or
11 approval granted prior to the enactment of the Food
12 Additives Amendment of 1958, pursuant to the federal act,
13 the Poultry Products Inspection Act (21 U.S.C. 451, et
14 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.
15 1260), as amended and extended (21 U.S.C. 71, et seq.).

16 ~~{15}~~(23) "Food service establishment" means a
17 restaurant, catering vehicle, vending machine, delicatessen,
18 fast-food retailer, or any other place that serves food to
19 the public for consumption either at or away from the point
20 of service, and any facility operated by a governmental
21 entity where food is served.

22 ~~{16}~~(24) "Hamburger" or "ground beef" means ground fresh
23 or frozen beef or a combination of both fresh and frozen
24 beef, with or without the addition of suet, to which no
25 water, binders, or extenders are added. There are three

1 grades of hamburger or ground beef:

2 (a) "economy hamburger" or "economy ground beef" may
3 have a fat content no greater than the federal standard set
4 forth in 9 C.F.R. 319.15;

5 (b) "regular hamburger" or "regular ground beef" may
6 have a fat content no greater than 21%;

7 (c) "extra lean hamburger" or "extra lean ground beef"
8 may have a fat content no greater than 18%.

9 ~~{17}~~(25) "Honey" means the nectar and saccharine
10 exudations of plants gathered, modified, and stored in the
11 comb by honey bees; is levorotatory, contains not more than
12 25% of water, not more than .25% of ash, and not more than
13 8% sucrose.

14 ~~{18}~~(26) "Label" means a display of written, printed, or
15 graphic matter on the immediate container of an article.
16 ("Immediate container" does not include package liners.)

17 ~~{19}~~(27) "Labeling" means labels and other written,
18 printed, or graphic matter:

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

20 (b) accompanying the article.

21 ~~{20}~~(28) "Menu" means any list presented to the patron
22 which states the food items for sale in a food service
23 establishment.

24 (29) "Mineral water" means water that contains more than
25 500 parts per million total dissolved mineral solids.

1 ~~(21)~~(30) "New drug" means a drug, the composition of
2 which is such that:

3 (a) it is not generally recognized, among experts
4 qualified by scientific training and experience to evaluate
5 the safety and effectiveness of drugs, as safe and effective
6 for use under the conditions prescribed, recommended, or
7 suggested in its labeling; or

8 (b) the drug, as a result of investigations to
9 determine its safety and effectiveness for use under the
10 conditions prescribed, has become so recognized but which
11 has not, otherwise than in the investigations, been used to
12 a material extent or for a material time under the
13 conditions prescribed.

14 ~~(22)~~(31) "Official compendium" means the official United
15 States Pharmacopoeia, official National Formulary, or a
16 supplement to either of these.

17 ~~(23)~~(32) "Organic food" means food that conforms to the
18 definition in 50-31-222.

19 ~~(24)~~(33) "Package" means a container or wrapping in
20 which a consumer commodity is enclosed for use in the
21 delivery or display of that consumer commodity to retail
22 purchasers but does not include:

23 (a) shipping containers or wrappings used solely for
24 the transportation of a consumer commodity in bulk or in
25 quantity to manufacturers, packers, or processors or to

1 wholesale or retail distributors;

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

6 ~~(25)~~(34) "Person" includes an individual, partnership,
7 corporation, and association.

8 ~~(26)~~(35) "Pesticide chemical" means a substance which
9 alone, in chemical combination, or in formulation with one
10 or more other substances is an "economic poison" under the
11 Federal Insecticide, Fungicide, and Rodenticide Act (7
12 U.S.C., secs. 135-135k), as amended, and which is used in
13 the production, storage, or transportation of raw
14 agricultural commodities.

15 ~~(27)~~(36) "Placard" means any nonpermanent sign used to
16 display or describe food items for sale in a food service
17 establishment or retail establishment.

18 ~~(28)~~(37) "Principal display panel" means that part of a
19 label that is most likely to be displayed, presented, shown,
20 or examined under normal and customary conditions of display
21 for retail sale.

22 ~~(29)~~(38) "Processing" means cooking, baking, heating,
23 drying, mixing, grinding, churning, separating, extracting,
24 cutting, freezing, or otherwise manufacturing a food or
25 changing the physical characteristics of a food, and the

1 enclosure of such food in a package.

2 (39) "Purified water" means water produced by
3 distillation, deionization, reverse osmosis, or other method
4 and that meets the definition of purified water in the 20th
5 edition of the pharmacopoeia of the United States of
6 America, 1980.

7 (39)(40) "Raw agricultural commodity" means food in its
8 raw or natural state, including fruits that are washed,
9 colored, or otherwise treated in their unpeeled natural form
10 prior to marketing.

11 (31)(41) "Retail establishment" means a commercial
12 establishment at which meat or meat products are displayed
13 for sale or provision to the public with or without charge.

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

18 (32)(43) "State board" or "board" means the board of
19 health and environmental sciences provided for in 2-15-2104.

20 (33)(44) "Synthetically compounded" means a product
21 formulated by a process that chemically changes a material
22 or substance extracted from naturally occurring plant,
23 animal, or mineral sources, except for microbiological
24 processes.

25 (45) "Water-bottling plant" means any facility in which

1 bottled water is produced.

2 (46) "Well water" means water that:

3 (a) is taken from below the ground through a piping
4 device or similar installed device utilizing external force
5 or vacuum;

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

7 (c) may have undergone minimum treatment consisting of:

8 (i) activated carbon or particulate filtration; and

9 (ii) ozonization or an equivalent disinfection
10 process."

11 **NEW SECTION. Section 2. Labeling requirements for**
12 **bottled water.** (1) A person may not sell, deliver, offer for
13 sale, hold for sale, or give away bottled water unless it
14 conforms to and is labeled in compliance with the following
15 standards:

16 (a) bottled mineral water must be labeled "mineral
17 water" or "natural mineral water";

18 (b) bottled water that contains naturally occurring
19 carbon dioxide that emerges from the water and is bottled
20 directly with its entrapped gas or that has been
21 mechanically separated from and subsequently reintroduced
22 into the water at a level not higher than that naturally
23 occurring in the water must be labeled "naturally carbonated
24 water" or "naturally sparkling water". Bottled water that
25 contains carbon dioxide from a source that is not naturally

occurring may not be labeled with the word "naturally".

(c) bottled artesian water may be labeled "artesian well water", "natural artesian water", or "natural well water";

(d) bottled spring water may be labeled "spring water" or "natural spring water";

(e) bottled well water may be labeled "well water" or "natural well water";

(f) bottled purified water must be labeled "purified water" and state the method of preparation. All of the letters specifying the type of bottled water must be printed in the same type size, style, and color. However, bottled purified water produced by distillation may be labeled "distilled water".

(g) bottled demineralized water that is not purified water must be labeled "demineralized water" and state the method of preparation. All of the letters specifying the type of bottled water must be printed in the same type size, style, and color. However, bottled demineralized water produced by distillation may be labeled "distilled water".

(h) bottled drinking water must be labeled "drinking water";

(i) bottled fluoridated water must specify on the label whether the fluoride is naturally occurring or added;

(j) unless the water is in fact spring water, language

containing the word "spring" or "springs" may not be used as a brand name on the label or in words describing the bottled water.

(2) A product meeting more than one definition may be labeled with any of the definitions with which it complies.

NEW SECTION. **Section 3. Health claims for bottled water.** Claims of medicinal or health-giving properties on labels or in advertisements for bottled water are prohibited.

NEW SECTION. **Section 4. Misrepresentation of a company name.** A bottler, distributor, or vendor of bottled water whose company name or trademark contains the words "spring", "springs", "well", "artesian well", "mineral", or any derivative of those words shall label each bottle with the company's brand name or trademark and, if the source of the bottled water is different from the source stated in the company name, the source of the water. This information must be in typeface at least equal to the size of the typeface of the company name or trademark.

Section 5. Section 50-31-110, MCA, is amended to read:
"50-31-110. Certain agricultural chemicals not color additives. Subsections ~~(3)~~ (7) and ~~(4)~~ (8) of 50-31-103 do not apply to a pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or

indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest."

Section 6. Section 50-31-208, MCA, is amended to read:

"50-31-208. Sale of hamburger and beef patty mix. (1)

No food service establishment or retail establishment may 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 establishment selling or serving beef patty mix may refer to the product as "beef patty mix" or by any other term which accurately informs the customer of the nature of the food product which he is sold or served.

(2) If beef patty mix is sold or served in a food service establishment or retail establishment, a list of ingredients must appear on the menu or label, or, if there is no menu or label, on a placard as follows:

(a) The term "beef patty mix" or any other term which 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 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 establishment, the grade, as defined in 50-31-103~~(16)~~(24), and the maximum fat 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 7. Section 50-31-312, MCA, is amended to read:

"50-31-312. Exemptions from new drug application requirement. (1) Section 50-31-311 shall 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;

(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;

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

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

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

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

12 (b) was not a new drug as defined by 50-31-103~~(2)~~(30)
13 as then in force; and

14 (c) was not covered by an effective application under
15 50-31-311 or under section 505 of the federal act."

16 NEW SECTION. **Section 8.** Codification instruction.
17 [Sections 2 through 4] are intended to be codified as an
18 integral part of Title 50, chapter 31, and the provisions of
19 Title 50, chapter 31, apply to [sections 2 through 4].

20 NEW SECTION. **Section 9.** Extension of authority. Any
21 existing authority to make rules on the subject of the
22 provisions of [this act] is extended to the provisions of
23 [this act].

-End-

STATE OF MONTANA - FISCAL NOTE

Form BD-15

In compliance with a written request, there is hereby submitted a Fiscal Note for HB684, as introduced.

DESCRIPTION OF PROPOSED LEGISLATION:

"An act to amend the Montana Food, Drug, and Cosmetic act to include regulation of bottled water; and amending Sections 50-31-103, 50-31-110, 50-31-208, and 50-31-312, MCA."

FISCAL IMPACT:

No fiscal impact



DATE

2/20/89

RAY SHACKLEFORD, BUDGET DIRECTOR
OFFICE OF BUDGET AND PROGRAM PLANNING



DATE

2/20/89

LARRY HAL GRINDE, PRIMARY SPONSOR

Fiscal Note for HB684, as introduced

HB 684

APPROVED BY COMM. ON
HUMAN SERVICES AND AGING

HOUSE BILL NO. 684

INTRODUCED BY GRINDE

A BILL FOR AN ACT ENTITLED: "AN ACT TO AMEND THE MONTANA
FOOD, DRUG, AND COSMETIC ACT TO INCLUDE REGULATION OF
BOTTLED WATER; AND AMENDING SECTIONS 50-31-103, 50-31-110,
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BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

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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 which 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 to TOWARD the surface through a well by
natural underground pressure.

(4) "Beef patty mix" means "hamburger" or "ground

beef" to which ~~has~~ have been added binders or extenders as
those terms are understood by general custom and usage in
the food industry.

(5) "Bottled water" means carbonated, demineralized,
distilled, fluoridated, mineral, purified, sparkling, or
other water that is from an approved source THAT IS
DISINFECTED and placed in a sealed container or package for
human consumption.

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

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

(8) (a) "Color additive" means a material which:

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

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

(b) This term does not include material which has been
or hereafter is exempted under the federal act.

(9) "Consumer commodity", except as otherwise
specifically provided by this subsection, means any food,

1 drug, device, or cosmetic as those terms are defined by this
2 chapter or by the federal act and regulations pursuant
3 thereto. The term does not include:

4 (a) any tobacco or tobacco product;

5 (b) a commodity subject to packaging or labeling
6 requirements imposed under the Federal Insecticide,
7 Fungicide, and Rodenticide Act or the provisions of the
8 eighth paragraph under the heading "Bureau of Animal
9 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21
10 U.S.C. 151-157), commonly known as the virus, serum, and
11 toxin act;

12 (c) a drug subject to 50-31-306(1)(m) or
13 50-31-307(1)(c) or section 503(b)(1) or 506 of the federal
14 act;

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

18 (e) a commodity subject to the Federal Seed Act (7
19 U.S.C. 1551-1610).

20 ~~(6)~~(10) "Contaminated with filth" applies to a food,
21 drug, device, or cosmetic not securely protected from dust,
22 dirt, and, as far as may be necessary by all reasonable
23 means, from foreign or injurious contaminations.

24 ~~(7)~~(11) "Cosmetic" means:

25 (a) articles intended to be rubbed, poured, sprinkled,

1 sprayed on, introduced into, or otherwise applied to the
2 human body for cleansing, beautifying, promoting
3 attractiveness, or altering the appearance;

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

6 ~~(8)~~(12) "Counterfeit drug" means a drug, drug
7 container, or drug label which, without authorization bears
8 the trademark, trade name, or other identifying mark,
9 imprint, or device or any likeness thereof of a drug
10 manufacturer, processor, packer, or distributor other than
11 the person who in fact manufactured, processed, packed, or
12 distributed the drug and which falsely purports or is
13 represented to be the product of or to have been packed or
14 distributed by the other drug manufacturer, processor,
15 packer, or distributor.

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

20 ~~(9)~~(14) "Department" means the department of health and
21 environmental sciences provided for in Title 2, chapter 15,
22 part 21.

23 ~~(10)~~(15) "Device" (except when used in 50-31-107(2),
24 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and
25 50-31-501(10)) means instruments, apparatus, and

1 contrivances, including their components, parts, and
2 accessories, intended:

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

5 (b) to affect the structure or function of the body of
6 man or other animals.

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

9 (17) "Drinking water" means water that has undergone
10 purification, distillation, demineralization,
11 mineralization, ACTIVATED CARBON OR PARTICULATE FILTRATION,
12 fluoridation, carbonation, or other similar process or has
13 undergone minimum treatment consisting of:

14 (a)--activated-carbon-or-particulate-filtration;-and
15 (b) ozonization or an equivalent ACCEPTABLE
16 disinfection process.

17 (11)(18) "Drug" means:

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

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

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

1 (d) articles intended for use as components of any
2 article specified in subsections (a), (b), or (c) but does
3 not include devices or their components, parts, or
4 accessories.

5 ~~(12)~~(19) "Federal act" means the Federal Food, Drug,
6 and Cosmetic Act, as amended (Title 21 U.S.C. 301, et seq.).

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

12 ~~(13)~~(21) "Food" means:

13 (a) articles used for food or drink for man or other
14 animals;

15 (b) chewing gum; and

16 (c) articles used for components of these articles.

17 ~~(14)~~(22) (a) "Food additive" means a substance, the
18 intended use of which results or may be reasonably expected
19 to result, directly or indirectly, in its becoming a
20 component or otherwise affecting the characteristics of food
21 (including a substance intended for use in producing,
22 manufacturing, packing, processing, preparing, treating,
23 packaging, transporting, or holding food and including a
24 source of radiation intended for this use), if the substance
25 is not generally recognized, among experts qualified by

1 scientific training and experience to evaluate its safety,
2 as having been adequately shown through scientific
3 procedures (or, in the case of a substance used in a food
4 prior to January 1, 1958, through either scientific
5 procedures or experience based on common use in food) to be
6 safe under the conditions of its intended use.

7 (b) This term does not include:

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

10 (ii) a pesticide chemical to the extent that it is
11 intended for use or is used in the production, storage, or
12 transportation of a raw agricultural commodity;

13 (iii) color additive;

14 (iv) substance used in accordance with a sanction or
15 approval granted prior to the enactment of the Food
16 Additives Amendment of 1958, pursuant to the federal act,
17 the Poultry Products Inspection Act (21 U.S.C. 451, et
18 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.
19 1260), as amended and extended (21 U.S.C. 71, et seq.).

20 ~~(15)~~(23) "Food service establishment" means a
21 restaurant, catering vehicle, vending machine, delicatessen,
22 fast-food retailer, or any other place that serves food to
23 the public for consumption either at or away from the point
24 of service, and any facility operated by a governmental
25 entity where food is served.

1 ~~(16)~~(24) "Hamburger" or "ground beef" means ground
2 fresh or frozen beef or a combination of both fresh and
3 frozen beef, with or without the addition of suet, to which
4 no water, binders, or extenders are added. There are three
5 grades of hamburger or ground beef:

6 (a) "economy hamburger" or "economy ground beef" may
7 have a fat content no greater than the federal standard set
8 forth in 9 C.F.R. 319.15;

9 (b) "regular hamburger" or "regular ground beef" may
10 have a fat content no greater than 21%;

11 (c) "extra lean hamburger" or "extra lean ground beef"
12 may have a fat content no greater than 18%.

13 ~~(17)~~(25) "Honey" means the nectar and saccharine
14 exudations of plants gathered, modified, and stored in the
15 comb by honey bees; is levorotatory, contains not more than
16 25% of water, not more than .25% of ash, and not more than
17 8% sucrose.

18 ~~(18)~~(26) "Label" means a display of written, printed,
19 or graphic matter on the immediate container of an article.
20 ("Immediate container" does not include package liners.)

21 ~~(19)~~(27) "Labeling" means labels and other written,
22 printed, or graphic matter:

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

24 (b) accompanying the article.

25 ~~(20)~~(28) "Menu" means any list presented to the patron

1 which states the food items for sale in a food service
2 establishment.

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

5 ~~(21)~~(30) "New drug" means a drug, the composition of
6 which is such that:

7 (a) it is not generally recognized, among experts
8 qualified by scientific training and experience to evaluate
9 the safety and effectiveness of drugs, as safe and effective
10 for use under the conditions prescribed, recommended, or
11 suggested in its labeling; or

12 (b) the drug, as a result of investigations to
13 determine its safety and effectiveness for use under the
14 conditions prescribed, has become so recognized but which
15 has not, otherwise than in the investigations, been used to
16 a material extent or for a material time under the
17 conditions prescribed.

18 ~~(22)~~(31) "Official compendium" means the official
19 United States Pharmacopoeia, official National Formulary, or
20 a supplement to either of these.

21 ~~(23)~~(32) "Organic food" means food that conforms to the
22 definition in 50-31-222.

23 ~~(24)~~(33) "Package" means a container or wrapping in
24 which a consumer commodity is enclosed for use in the
25 delivery or display of that consumer commodity to retail

1 purchasers but does not include:

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

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

10 ~~(25)~~(34) "Person" includes an individual, partnership,
11 corporation, and association.

12 ~~(26)~~(35) "Pesticide chemical" means a substance which
13 alone, in chemical combination, or in formulation with one
14 or more other substances is an "economic poison" under the
15 Federal Insecticide, Fungicide, and Rodenticide Act (7
16 U.S.C., secs. 135-135k), as amended, and which is used in
17 the production, storage, or transportation of raw
18 agricultural commodities.

19 ~~(27)~~(36) "Placard" means any nonpermanent sign used to
20 display or describe food items for sale in a food service
21 establishment or retail establishment.

22 ~~(28)~~(37) "Principal display panel" means that part of a
23 label that is most likely to be displayed, presented, shown,
24 or examined under normal and customary conditions of display
25 for retail sale.

1 ~~(29)~~(38) "Processing" means cooking, baking, heating,
2 drying, mixing, grinding, churning, separating, extracting,
3 cutting, freezing, or otherwise manufacturing a food or
4 changing the physical characteristics of a food, and the
5 enclosure of such food in a package.

6 (39) "Purified water" means water produced by
7 distillation, deionization, reverse osmosis, or other method
8 and that meets the definition of purified water in the 20th
9 edition of the pharmacopoeia of the United States of
10 America, 1980.

11 ~~(30)~~(40) "Raw agricultural commodity" means food in its
12 raw or natural state, including fruits that are washed,
13 colored, or otherwise treated in their unpeeled natural form
14 prior to marketing.

15 ~~(31)~~(41) "Retail establishment" means a commercial
16 establishment at which meat or meat products are displayed
17 for sale or provision to the public with or without charge.

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

22 ~~(32)~~(43) "State board" or "board" means the board of
23 health and environmental sciences provided for in 2-15-2104.

24 ~~(33)~~(44) "Synthetically compounded" means a product
25 formulated by a process that chemically changes a material

1 or substance extracted from naturally occurring plant,
2 animal, or mineral sources, except for microbiological
3 processes.

4 (45) "Water-bottling plant" means any facility in which
5 bottled water is produced.

6 (46) "Well water" means water that:

7 (a) is taken from below the ground through a piping
8 device or similar installed device utilizing external force
9 or vacuum;

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

11 (c) may have undergone minimum treatment consisting
12 of:

13 ~~fi)~~--activated-carbon-or-particulate-filtration; and

14 ~~fi)~~ ozonization or an equivalent ACCEPTABLE
15 disinfection process."

16 NEW SECTION. Section 2. Labeling requirements for
17 bottled water. (1) A person may not sell, deliver, offer for
18 sale, hold for sale, or give away bottled water unless it
19 conforms to and is labeled in compliance with the following
20 standards:

21 (a) bottled mineral water must be labeled "mineral
22 water" or "natural mineral water";

23 (b) bottled water that contains naturally occurring
24 carbon dioxide that emerges from the water and is bottled
25 directly with its entrapped gas or that has been

mechanically separated from and subsequently reintroduced into the water at a level not higher than that naturally occurring in the water must be labeled "naturally carbonated water" or "naturally sparkling water". Bottled water that contains carbon dioxide from a source that is not naturally occurring may not be labeled with the word "naturally".

(c) bottled artesian water may be labeled "artesian well water", "natural artesian water", or "natural well water";

(d) bottled spring water may be labeled "spring water" or "natural spring water";

(e) bottled well water may be labeled "well water" or "natural well water";

(f) bottled purified water must be labeled "purified water" and state the method of preparation. All of the letters specifying the type of bottled water must be printed in the same type size, style, and color. However, bottled purified water produced by distillation may be labeled "distilled water".

(g) bottled demineralized water that is not purified water must be labeled "demineralized water" and state the method of preparation. All of the letters specifying the type of bottled water must be printed in the same type size, style, and color. However, bottled demineralized water produced by distillation may be labeled "distilled water".

(h) bottled drinking water must be labeled "drinking water";

(i) bottled fluoridated water must specify on the label whether the fluoride is naturally occurring or added;

(j) unless the water is in fact spring water, language containing the word "spring" or "springs" may not be used as a brand name on the label or in words describing the bottled water.

(2) A product meeting more than one definition may be labeled with any of the definitions with which it complies.

NEW SECTION. **Section 3. Health claims for bottled water.** Claims of medicinal or health-giving properties on labels or in advertisements for bottled water are prohibited.

NEW SECTION. **Section 4. Misrepresentation of a company name.** A bottler, distributor, or vendor of bottled water whose company name or trademark contains the words "spring", "springs", "well", "artesian well", "mineral", or any derivative of those words shall label each bottle with the company's brand name or trademark and, if the source of the bottled water is different from the source stated in the company name, the source of the water. This information must be in typeface at least equal to the size of the typeface of the company name or trademark.

Section 5. Section 50-31-110, MCA, is amended to read:

1 "50-31-110. Certain agricultural chemicals not color
2 additives. Subsections ~~(3)~~ (7) and ~~(4)~~ (8) of 50-31-103 do
3 not apply to a pesticide chemical, soil or plant nutrient,
4 or other agricultural chemical solely because of its effect
5 in aiding, retarding, or otherwise affecting, directly or
6 indirectly, the growth or other natural physiological
7 process of produce of the soil and thereby affecting its
8 color, whether before or after harvest."

9 **Section 6.** Section 50-31-208, MCA, is amended to read:

10 "50-31-208. Sale of hamburger and beef patty mix. (1)
11 No food service establishment or retail establishment may
12 use the terms "hamburger", "burger", or other similar term
13 in any advertisement or menu to refer to any beef patty mix.
14 A food service establishment or retail establishment selling
15 or serving beef patty mix may refer to the product as "beef
16 patty mix" or by any other term which accurately informs the
17 customer of the nature of the food product which he is sold
18 or served.

19 (2) If beef patty mix is sold or served in a food
20 service establishment or retail establishment, a list of
21 ingredients must appear on the menu or label, or, if there
22 is no menu or label, on a placard as follows:

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

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

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

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

9 (3) If hamburger or ground beef is sold in a retail
10 establishment, the grade, as defined in 50-31-103~~(16)~~(24),
11 and the maximum fat content must appear on each displayed
12 package, or if the product is not packaged for display, on a
13 placard. If a placard is used, it must satisfy the
14 requirements of subsections (2)(c) and (2)(d) of this
15 section. The provisions of this subsection do not apply to
16 the service of prepared hamburger or ground beef at a food
17 service establishment."

18 **Section 7.** Section 50-31-312, MCA, is amended to read:

19 "50-31-312. Exemptions from new drug application
20 requirement. (1) Section 50-31-311 shall not apply to:

21 (a) a drug intended solely for investigational use by
22 experts qualified by scientific training and experience to
23 investigate the safety and effectiveness of drugs, provided
24 the drug is plainly labeled in compliance with regulations
25 issued by the department or pursuant to section 505(i) or

1 507(d) of the federal act;

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

6 (c) any drug which is licensed under the Virus, Serum,
7 and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. Title 42,
8 chapter 6A, sec. 262); or

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

10 (2) The provisions of 50-31-103~~(2)~~(30) shall not
11 apply to any drug, when such drug is intended solely for use
12 under conditions prescribed, recommended, or suggested in
13 labeling with respect to such drug, which on October 9,
14 1962, or on the date immediately preceding July 1, 1967:

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

17 (b) was not a new drug as defined by 50-31-103~~(2)~~(30)
18 as then in force; and

19 (c) was not covered by an effective application under
20 50-31-311 or under section 505 of the federal act."

21 NEW SECTION. Section 8. Codification instruction.
22 [Sections 2 through 4] are intended to be codified as an
23 integral part of Title 50, chapter 31, and the provisions of
24 Title 50, chapter 31, apply to [sections 2 through 4].

25 NEW SECTION. Section 9. Extension of authority. Any

1 existing authority to make rules on the subject of the
2 provisions of [this act] is extended to the provisions of
3 [this act].

-End-

APPROVED BY COMM. ON
HUMAN SERVICES AND AGINGHOUSE BILL NO. 684
INTRODUCED BY GRINDE

A BILL FOR AN ACT ENTITLED: "AN ACT TO AMEND THE MONTANA
FOOD, DRUG, AND COSMETIC ACT TO INCLUDE REGULATION OF
BOTTLED WATER; AND AMENDING SECTIONS 50-31-103, 50-31-110,
50-31-208, AND 50-31-312, 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 which 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 to TOWARD the surface through a well by
natural underground pressure.

(4) "Beef patty mix" means "hamburger" or "ground

There is no change on HB 684 and will not be
reprinted. Please refer to second reading
(yellow) for complete text.

HOUSE BILL NO. 684

INTRODUCED BY GRINDE

A BILL FOR AN ACT ENTITLED: "AN ACT TO AMEND THE MONTANA FOOD, DRUG, AND COSMETIC ACT TO INCLUDE REGULATION OF BOTTLED WATER; AND AMENDING SECTIONS 50-31-103, 50-31-110, 50-31-208, AND 50-31-312, 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 which 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 to TOWARD the surface through a well by natural underground pressure.

(4) "Beef patty mix" means "hamburger" or "ground

beef" to which has have been added binders or extenders as those terms are understood by general custom and usage in the food industry.

(5) "Bottled water" means carbonated, demineralized, distilled, fluoridated, mineral, purified, sparkling, or other water that is from an approved source THAT IS DISINFECTED and placed in a sealed container or package for human consumption.

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

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

(8) (a) "Color additive" means a material which:

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

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

(b) This term does not include material which has been or hereafter is exempted under the federal act.

(9) "Consumer commodity", except as otherwise specifically provided by this subsection, means any food,

1 drug, device, or cosmetic as those terms are defined by this
2 chapter or by the federal act and regulations pursuant
3 thereto. The term does not include:

4 (a) any tobacco or tobacco product;

5 (b) a commodity subject to packaging or labeling
6 requirements imposed under the Federal Insecticide,
7 Fungicide, and Rodenticide Act or the provisions of the
8 eighth paragraph under the heading "Bureau of Animal
9 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21
10 U.S.C. 151-157), commonly known as the virus, serum, and
11 toxin act;

12 (c) a drug subject to 50-31-306(1)(m) or
13 50-31-307(1)(c) or section 503(b)(1) or 506 of the federal
14 act;

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

18 (e) a commodity subject to the Federal Seed Act (7
19 U.S.C. 1551-1610).

20 {6}{10} "Contaminated with filth" applies to a food,
21 drug, device, or cosmetic not securely protected from dust,
22 dirt, and, as far as may be necessary by all reasonable
23 means, from foreign or injurious contaminations.

24 {7}{11} "Cosmetic" means:

25 (a) articles intended to be rubbed, poured, sprinkled,

1 sprayed on, introduced into, or otherwise applied to the
2 human body for cleansing, beautifying, promoting
3 attractiveness, or altering the appearance;

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

6 {8}{12} "Counterfeit drug" means a drug, drug
7 container, or drug label which, without authorization bears
8 the trademark, trade name, or other identifying mark,
9 imprint, or device or any likeness thereof of a drug
10 manufacturer, processor, packer, or distributor other than
11 the person who in fact manufactured, processed, packed, or
12 distributed the drug and which falsely purports or is
13 represented to be the product of or to have been packed or
14 distributed by the other drug manufacturer, processor,
15 packer, or distributor.

16 {13} "Demineralized water" means water that has been
17 demineralized by distillation, deionization, reverse
18 osmosis, or other methods and contains not more than 10
19 parts per million total solids.

20 {9}{14} "Department" means the department of health and
21 environmental sciences provided for in Title 2, chapter 15,
22 part 21.

23 {10}{15} "Device" (except when used in 50-31-107(2),
24 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and
25 50-31-501(10)) means instruments, apparatus, and

1 contrivances, including their components, parts, and
2 accessories, intended:

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

5 (b) to affect the structure or function of the body of
6 man or other animals.

7 {16} "Distilled water" means purified water that has
8 been vaporized and condensed.

9 {17} "Drinking water" means water that has undergone
10 purification, distillation, demineralization,
11 mineralization, ACTIVATED CARBON OR PARTICULATE FILTRATION,
12 fluoridation, carbonation, or other similar process or has
13 undergone minimum treatment consisting of:

14 ~~{a}--activated-carbon-or-particulate-filtration; and~~
15 ~~{b} ozonization or an equivalent ACCEPTABLE~~
16 disinfection process.

17 ~~{11}{18}~~ "Drug" means:

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

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

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

1 (d) articles intended for use as components of any
2 article specified in subsections (a), (b), or (c) but does
3 not include devices or their components, parts, or
4 accessories.

5 ~~{12}{19}~~ "Federal act" means the Federal Food, Drug,
6 and Cosmetic Act, as amended (Title 21 U.S.C. 301, et seq.).

7 {20} "Fluoridated water" means water that contains,
8 naturally or by addition, fluoride ions in quantities of not
9 less than 0.7 and not more than 1.4 milligrams per liter and
10 complies with the food and drug administration quality
11 standards set forth in 21 CFR 103.35.

12 ~~{13}{21}~~ "Food" means:

13 (a) articles used for food or drink for man or other
14 animals;

15 (b) chewing gum; and

16 (c) articles used for components of these articles.

17 ~~{14}{22}~~ (a) "Food additive" means a substance, the
18 intended use of which results or may be reasonably expected
19 to result, directly or indirectly, in its becoming a
20 component or otherwise affecting the characteristics of food
21 (including a substance intended for use in producing,
22 manufacturing, packing, processing, preparing, treating,
23 packaging, transporting, or holding food and including a
24 source of radiation intended for this use), if the substance
25 is not generally recognized, among experts qualified by

1 scientific training and experience to evaluate its safety,
 2 as having been adequately shown through scientific
 3 procedures (or, in the case of a substance used in a food
 4 prior to January 1, 1958, through either scientific
 5 procedures or experience based on common use in food) to be
 6 safe under the conditions of its intended use.

7 (b) This term does not include:

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

10 (ii) a pesticide chemical to the extent that it is
 11 intended for use or is used in the production, storage, or
 12 transportation of a raw agricultural commodity;

13 (iii) color additive;

14 (iv) substance used in accordance with a sanction or
 15 approval granted prior to the enactment of the Food
 16 Additives Amendment of 1958, pursuant to the federal act,
 17 the Poultry Products Inspection Act (21 U.S.C. 451, et
 18 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.
 19 1260), as amended and extended (21 U.S.C. 71, et seq.).

20 ~~§15~~(23) "Food service establishment" means a
 21 restaurant, catering vehicle, vending machine, delicatessen,
 22 fast-food retailer, or any other place that serves food to
 23 the public for consumption either at or away from the point
 24 of service, and any facility operated by a governmental
 25 entity where food is served.

1 ~~§16~~(24) "Hamburger" or "ground beef" means ground
 2 fresh or frozen beef or a combination of both fresh and
 3 frozen beef, with or without the addition of suet, to which
 4 no water, binders, or extenders are added. There are three
 5 grades of hamburger or ground beef:

6 (a) "economy hamburger" or "economy ground beef" may
 7 have a fat content no greater than the federal standard set
 8 forth in 9 C.F.R. 319.15;

9 (b) "regular hamburger" or "regular ground beef" may
 10 have a fat content no greater than 21%;

11 (c) "extra lean hamburger" or "extra lean ground beef"
 12 may have a fat content no greater than 18%.

13 ~~§17~~(25) "Honey" means the nectar and saccharine
 14 exudations of plants gathered, modified, and stored in the
 15 comb by honey bees; is levorotatory, contains not more than
 16 25% of water, not more than .25% of ash, and not more than
 17 8% sucrose.

18 ~~§18~~(26) "Label" means a display of written, printed,
 19 or graphic matter on the immediate container of an article.
 20 ("Immediate container" does not include package liners.)

21 ~~§19~~(27) "Labeling" means labels and other written,
 22 printed, or graphic matter:

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

24 (b) accompanying the article.

25 ~~§20~~(28) "Menu" means any list presented to the patron

1 which states the food items for sale in a food service
2 establishment.

3 {29} "Mineral water" means water that contains more
4 than 500 parts per million total dissolved mineral solids.

5 {21}{30} "New drug" means a drug, the composition of
6 which is such that:

7 (a) it is not generally recognized, among experts
8 qualified by scientific training and experience to evaluate
9 the safety and effectiveness of drugs, as safe and effective
10 for use under the conditions prescribed, recommended, or
11 suggested in its labeling; or

12 (b) the drug, as a result of investigations to
13 determine its safety and effectiveness for use under the
14 conditions prescribed, has become so recognized but which
15 has not, otherwise than in the investigations, been used to
16 a material extent or for a material time under the
17 conditions prescribed.

18 {22}{31} "Official compendium" means the official
19 United States Pharmacopoeia, official National Formulary, or
20 a supplement to either of these.

21 {23}{32} "Organic food" means food that conforms to the
22 definition in 50-31-222.

23 {24}{33} "Package" means a container or wrapping in
24 which a consumer commodity is enclosed for use in the
25 delivery or display of that consumer commodity to retail

1 purchasers but does not include:

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

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

10 {25}{34} "Person" includes an individual, partnership,
11 corporation, and association.

12 {26}{35} "Pesticide chemical" means a substance which
13 alone, in chemical combination, or in formulation with one
14 or more other substances is an "economic poison" under the
15 Federal Insecticide, Fungicide, and Rodenticide Act (7
16 U.S.C., secs. 135-135k), as amended, and which is used in
17 the production, storage, or transportation of raw
18 agricultural commodities.

19 {27}{36} "Placard" means any nonpermanent sign used to
20 display or describe food items for sale in a food service
21 establishment or retail establishment.

22 {28}{37} "Principal display panel" means that part of a
23 label that is most likely to be displayed, presented, shown,
24 or examined under normal and customary conditions of display
25 for retail sale.

~~(29)~~(38) "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 such food in a package.

(39) "Purified water" means water 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.

~~(30)~~(40) "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.

~~(31)~~(41) "Retail establishment" means a commercial establishment at which meat or meat products are displayed for sale or provision to the public with or without charge.

(42) "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.

~~(32)~~(43) "State board" or "board" means the board of health and environmental sciences provided for in 2-15-2104.

~~(33)~~(44) "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.

(45) "Water-bottling plant" means any facility in which bottled water is produced.

(46) "Well water" means water that:

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

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

(c) may have undergone minimum treatment consisting of:

~~iii~~--activated-carbon-or-particulate-filtration; and

~~iii~~ ozonization or an equivalent ACCEPTABLE disinfection process."

NEW SECTION. Section 2. Labeling requirements for bottled water. (1) A person may not sell, deliver, offer for sale, hold for sale, or give away bottled water unless it conforms to and is labeled in compliance with the following standards:

(a) bottled mineral water must be labeled "mineral water" or "natural mineral water";

(b) bottled water that contains naturally occurring carbon dioxide that emerges from the water and is bottled directly with its entrapped gas or that has been

1 mechanically separated from and subsequently reintroduced
 2 into the water at a level not higher than that naturally
 3 occurring in the water must be labeled "naturally carbonated
 4 water" or "naturally sparkling water". Bottled water that
 5 contains carbon dioxide from a source that is not naturally
 6 occurring may not be labeled with the word "naturally".

7 (c) bottled artesian water may be labeled "artesian
 8 well water", "natural artesian water", or "natural well
 9 water";

10 (d) bottled spring water may be labeled "spring water"
 11 or "natural spring water";

12 (e) bottled well water may be labeled "well water" or
 13 "natural well water";

14 (f) bottled purified water must be labeled "purified
 15 water" and state the method of preparation. All of the
 16 letters specifying the type of bottled water must be
 17 printed in the same type size, style, and color. However,
 18 bottled purified water produced by distillation may be
 19 labeled "distilled water".

20 (g) bottled demineralized water that is not purified
 21 water must be labeled "demineralized water" and state the
 22 method of preparation. All of the letters specifying the
 23 type of bottled water must be printed in the same type size,
 24 style, and color. However, bottled demineralized water
 25 produced by distillation may be labeled "distilled water".

1 (h) bottled drinking water must be labeled "drinking
 2 water";

3 (i) bottled fluoridated water must specify on the
 4 label whether the fluoride is naturally occurring or added;

5 (j) unless the water is in fact spring water, language
 6 containing the word "spring" or "springs" may not be used as
 7 a brand name on the label or in words describing the bottled
 8 water.

9 (2) A product meeting more than one definition may be
 10 labeled with any of the definitions with which it complies.

11 NEW SECTION. **Section 3. Health claims for bottled**
 12 **water.** Claims of medicinal or health-giving properties on
 13 labels or in advertisements for bottled water are
 14 prohibited.

15 NEW SECTION. **Section 4. Misrepresentation of a**
 16 **company name.** A bottler, distributor, or vendor of bottled
 17 water whose company name or trademark contains the words
 18 "spring", "springs", "well", "artesian well", "mineral", or
 19 any derivative of those words shall label each bottle with
 20 the company's brand name or trademark and, if the source of
 21 the bottled water is different from the source stated in the
 22 company name, the source of the water. This information must
 23 be in typeface at least equal to the size of the typeface of
 24 the company name or trademark.

25 **Section 5.** Section 50-31-110, MCA, is amended to read:

1 **"50-31-110. Certain agricultural chemicals not color**
 2 **additives. Subsections (3) (7) and (4) (8) of 50-31-103 do**
 3 **not apply to a pesticide chemical, soil or plant nutrient,**
 4 **or other agricultural chemical solely because of its effect**
 5 **in aiding, retarding, or otherwise affecting, directly or**
 6 **indirectly, the growth or other natural physiological**
 7 **process of produce of the soil and thereby affecting its**
 8 **color, whether before or after harvest."**

9 **Section 6. Section 50-31-208, MCA, is amended to read:**

10 **"50-31-208. Sale of hamburger and beef patty mix. (1)**
 11 **No food service establishment or retail establishment may**
 12 **use the terms "hamburger", "burger", or other similar term**
 13 **in any advertisement or menu to refer to any beef patty mix.**
 14 **A food service establishment or retail establishment selling**
 15 **or serving beef patty mix may refer to the product as "beef**
 16 **patty mix" or by any other term which accurately informs the**
 17 **customer of the nature of the food product which he is sold**
 18 **or served.**

19 **(2) If beef patty mix is sold or served in a food**
 20 **service establishment or retail establishment, a list of**
 21 **ingredients must appear on the menu or label, or, if there**
 22 **is no menu or label, on a placard as follows:**

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

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

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

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

9 **(3) If hamburger or ground beef is sold in a retail**
 10 **establishment, the grade, as defined in 50-31-103(16)(24),**
 11 **and the maximum fat content must appear on each displayed**
 12 **package, or if the product is not packaged for display, on a**
 13 **placard. If a placard is used, it must satisfy the**
 14 **requirements of subsections (2)(c) and (2)(d) of this**
 15 **section. The provisions of this subsection do not apply to**
 16 **the service of prepared hamburger or ground beef at a food**
 17 **service establishment."**

18 **Section 7. Section 50-31-312, MCA, is amended to read:**

19 **"50-31-312. Exemptions from new drug application**
 20 **requirement. (1) Section 50-31-311 shall not apply to:**

21 **(a) a drug intended solely for investigational use by**
 22 **experts qualified by scientific training and experience to**
 23 **investigate the safety and effectiveness of drugs, provided**
 24 **the drug is plainly labeled in compliance with regulations**
 25 **issued by the department or pursuant to section 505(f) or**

1 507(d) of the federal act;

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

6 (c) any drug which is licensed under the Virus, Serum,
7 and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. Title 42,
8 chapter 6A, sec. 262); or

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

10 (2) The provisions of 50-31-103~~(2)~~(30) shall not
11 apply to any drug, when such drug is intended solely for use
12 under conditions prescribed, recommended, or suggested in
13 labeling with respect to such drug, which on October 9,
14 1962, or on the date immediately preceding July 1, 1967:

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

17 (b) was not a new drug as defined by 50-31-103~~(2)~~(30)
18 as then in force; and

19 (c) was not covered by an effective application under
20 50-31-311 or under section 505 of the federal act."

21 NEW SECTION. Section 8. Codification instruction.
22 [Sections 2 through 4] are intended to be codified as an
23 integral part of Title 50, chapter 31, and the provisions of
24 Title 50, chapter 31, apply to [sections 2 through 4].

25 NEW SECTION. Section 9. Extension of authority. Any

1 existing authority to make rules on the subject of the
2 provisions of [this act] is extended to the provisions of
3 [this act].

-End-