CHAPTER NO. 456____.

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HOUSE BILL NO. 316

INTRODUCED BY HAND, CONROY, O'CONNELL, LIEN, STAIGMILLER, JOHNSON, WOOD, KEYSER, MARKS, JOHNSTON, PAVLOVICH, McBRIDE, MANUEL, QUILICI, K. ROBBINS, JENSEN, PISTORIA, CURTISS, GOULD, NATHE, LUND, COONEY

IN THE HOUSE

January 23, 1979	Introduced and referred to Committee on Business and Industry.
January 31, 1979	Committee recommend bill do pass as amended. Report adopted.
February 1, 1979	Printed and placed on members' desks.
February 2, 1979	Second reading, do pass.
February 3, 1979	Considered correctly engrossed.
February 5, 1979	Third reading, passed. Transmitted to second house.
IN	THE SENATE
February 6, 1979	Introduced and referred to Committee on Business and Industry.
February 28, 1979	On motion, taken from Com- mittee on Business and Industry. Referred to Committee on Public Health, Welfare, and Safety.
March 15, 1979	Committee recommend bill be concurred in. Report adopted.
March 17, 1979	Second reading, concurred in.
March 20, 1979	Third reading, concurred in.

IN THE HOUSE

March 21, 1979

Returned from second house. Concurred in. Sent to enrolling.

Reported correctly enrolled.

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HOLDE BILL NO. 316 AAN ACT 10 REQUIRE FOOD SERVICE A BILL FOR AN ACT ENTITLED: ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND INITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE AND TO ADVERTISE THE LIST OF INGREDIENTS IN IMITATION HAHBURGER; AND AMENDING SECTIONS 50-31-103, 50-31-312, 50-31-506, AND 50-31-508, KCA.*

11 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA: 12 Section 1. Section 50-31-103, MCA, is amended to read: 13 "50-31-103. Definitions. Unless the context requires otherwise, in this chapter the following definitions apply: 14 (1) "Advertisement" means representations disseminated 15 in any manner or by any means, other than by labeling, for 16 17 the purpose of inducing or which are likely to induce, 18 directly or indirectly, the purchase of food, urugs, devices, or cosmetics. 19

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

22 (3) (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

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

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

8 (4) "Consumer commodity", except as otherwise
9 specifically provided by this subsection, means any food,
10 drug, device, or cosmetic as those terms are defined by this
11 chapter or by the federal act and regulations pursuant
12 thereto. The term does not include:

13 (a) any tobacco or tobacco product;

14 (b) a commodity subject to packaging or labeling 15 requirements imposed under the Federal Insecticide. 16 Fungicide, and Rodenticide Act or the provisions of the 17 eighth paragraph under the heading "Bureau of Animal 18 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21 19 U.S.C. 151-157), commonly known as the virus-serum toxin 20 act;

21 (c) a drug subject to [section 17(a)(B) or 16(k) of 22 this act] or section \$03(b)(1) or 506 of the federal act;

23 (d) a beverage subject to or complying with packaging

24 or labeling requirements imposed under the Federal Alcohol

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25 Administration Act (27 U+S+C++ et seq+); or 月10

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INTRÓDUCED BILL

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

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

(6) "Cosmetic" means:

7

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

12 (b) articles intended for use as a component of these13 articles, except that the term does not include soap.

14 (7) "Counterfeit drug" means, a drug which, or the container or labeling of which, without authorization bears 15 16 the trademark, trade name, or other identifying mark, 17 imprint, or device or any likeness thereof of a drug manufacturer, processor, packer, or distributor other than 18 the person who in fact manufactured, processed, packed, or 19 20 distributed the drug and which falsely purports or is 21 represented to be the product of or to have been packed or 22 distributed by the other drug manufacturer, processor, 23 packer, or distributor.

24 (8) "Department" means the department of health and
25 environmental sciences, provided for in Title 2, chapter 15,

1 part 21.

2 (9) "Device" (except when used in 50-31-107(2), 3 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and 4 50-31-501(10)) means instruments, apparatus, and 5 contrivances, including their components, parts, and 6 accessories, intended:

7 (a) for use in the diagnosis, cure, mitigation,
a treatment, or prevention of disease in man or other animals;
9 (b) to affect the structure or function of the body of
10 man or other animals.

11 (10) "Orug" means:

12 (a) articles recognized in the official United States
13 Pharmacopoeia, official Homeopathic Pharmacopoeia of the
14 United States, or official National Formulary or a
15 supplement to any of these;

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

19 (c) articles (other than food) intended to affect the 20 structure or function of the body of man or other animals; 21 (d) articles intended for use as components of any 22 article specified in subsections (a), (b), or (c), but does 23 not include devices or their components, parts, or 24 accessories.

25 (11) "Federal act" means the Federal Food, Drug, and

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Cosmetic Act, as amended (Title 21 U.S.C. 301 et sed.). 1 (12) "Food" means: 2 (a) articles used for food or drink for man or other 3 animals: 4 (b) chewing gum; and 5 (c) articles used for components of these articles. 6 7 (13) (a) "Food additive" means a substance, the intended use of which results or may be reasonably expected 8 to result, directly or indirectly, in its becoming a 9 component or otherwise affecting the characteristics of food 10 (including a substance intended for use in producing, 11 manufacturing, packing, processing, preparing, treating, 12 packaging, transporting, or holding food and including a 13 source of radiation intended for this use; if the substance 14 is not generally recognized, among experts qualified by 15 scientific training and experience to evaluate its safety. 16 as having been adequately shown through scientific 17 procedures (or, in the case of a substance used in a food 18 prior to January 1, 1958, through either scientific 19 procedures or experience based on common use in food) to be 20 21 safe under the conditions of its intended use.

22 (b) This term does not include:

(i) a pesticide chemical in or on a raw agricultural 23 commodity; 24

(ii) a pesticide chemical to the extent that it is 25

intended for use or is used in the production, storage, or 1 transportation of a raw agricultural commodity; 2

3 (iii) color additive;

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(iv) substance used in accordance with a sanction or * approval granted prior to the enactment of the Food 5 Additives Amendment of 1958, pursuant to the federal act, 6 7 the Poultry Products Inspection Act (2) U.S.C. 451 et seq.). A or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260). 9 as amended and extended (21 U.S.C. 71 et seq.). (14) "Food service establishment" means a restaurant. 10 catering vehicle. vehicle achine. delicatesses. fast-food 11 12 retailer, or any other place that serves food to the public for consumption either at or away from the point of services 13 14 and any facility operated by a governmental entity where 15 food is served. 16 (15) "Hamburger" means comminuted fresh or frozen beef 17 or a combination of both fresh and frozen beefs with or without the addition of suct and with or without the 18 addition of seasoning, if no fat other than suct is 19 incorporated in the hamburger, the total fat content does 20 not exceed 20% and no water, binders, or extenders are 21 22 added. fid(16) "Honey" means the nectar and saccharine 23 exudations of plants gathered, modified, and stored in the 24

comb by honey bees; is levorotatory, contains not more than

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1	25% of water, not more than .25% of ash, and not more than
z	8% sucrose.
3	(17) "Imitationbamburger"means"hamburger"as
4	defined in subsection (14), to which has been added binders
5	or extenders or both binders and extenders as those terms
6	are understood by general custom and usage in the food
7	industrye
8	<pre>tister: "Label" means a display of written; printed;</pre>
9	or graphic matter on the immediate container of an article.
10	("lmmediate container" does not include package liners.)
11	<pre>fl6j[19] "Labeling" means labels and other written;</pre>
12	printed, or graphic matter:
13	(a) on an article or its containers or wrappers;
14	(b) accompanying the article.
15	[20] "Menu" means any list presented to the patron
16	which states the food items for sale in a food service
17	<u>establishment.</u>
18	[]]][2]] "New drug" means a drug the composition of
19	which is such that:
20	(a) it is not generally recognized, among experts
21	qualified by scientific training and experience to evaluate
2 2	the safety and effectiveness of drugs, as safe and effective
23	for use under the conditions prescribed: recommended, or
24	suggested in its labeling; or

25 (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 which
 has not, otherwise than in the investigations, been used to
 a material extent or for a material time under the
 conditions prescribed.

6 (18)(22) "Official compendium" means the official
7 United States Pharmacopoeia, official Homeopathic
8 Pharmacopoeia of the United States, official National
9 Formulary, or a supplement to any of these.

10 <u>ft9f(23)</u> "Package" means a container or wrapping in 11 which a consumer commodity is enclosed for use in the 12 delivery or display of that consumer commodity to retail 13 purchasers but does not include:

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

18 (b) shipping containers or outer wrappings used ty 19 retailers to ship or deliver a commodity to retail customers 20 if the containers and wrappings bear no printed matter 21 pertaining to a particular commodity.

t20+(24) "Person" includes an individual, partnership.
 corporation. and association.

24 f2l+(25) *Pesticide chemical* means a substance with.
25 alonn+ in chemical combination+ or in formulation with one

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or more other substances, is an "economic poison" under the
 Federal Insecticide, Fungicide, and Rodenticide Act {7
 U.S.C., secs. 135-135k), as amended, and which is used in
 the production, storage, or transportation of raw
 agricultural commodities.

6 <u>(26) "Placard" means any conpermanent sign used to</u>
7 <u>display or describe food items for sale in a food service</u>
8 establishment.

9 <u>t22)(27)</u> "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.

13 (23)(28) "Raw agricultural commodity" means food in its
14 raw or natural state, including fruits that are washed,
15 colored, or otherwise treated in their unpeeled natural form
16 prior to marketing.

17 (24)[29] "State board" or "board" means the board of 18 health and environmental sciences, provided for in 19 2-15-2104.

20 (30) "Hallboard" means any permanent sign used to
 21 display or describe food items for sale in a food service
 22 establishment."

23 Section 2. Section 50-31-312. MCA. is amended to read:
24 "50-31-312. Exemptions from new drug application
25 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

6 507(d) of the federal act;

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

(c) any drug which is Ficensed under the Virus, Serum,
 and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. Title 42,
 chapter 6A, sec. 2621; or

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

15 (2) The provisions of 50-31-103(17)(21) shall not 16 apply to any drug, when such drug is intended solely for use 17 under conditions prescribed, recommended, or suggested in 18 labeling with respect to such drug, which on October 9, 19 1962, or on the date immediately preceding July 1, 1967:

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

22 (b) was not a new drug as defined by 50-31-103(17)(21)

23 as then in force; and

24 (c) was not covered by an effective application under

25 50-31-311 or under section 505 of the federal act."

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Section 3. Section 50-31-506, MCA. is amended to read:
 "50-31-506. Penalties. (1) Any person who violates any
 of the provisions of 50-31-204, 50-31-501, or 50-31-502<u>x...gr</u>
 <u>[section.5.of.this.act]</u> shall be guilty of a misdemeanor and
 shall on conviction thereof be subject to imprisonment for
 not more than 3 months. a fine of not more than \$250. or
 both such imprisonment and fine.

8 (2) If the violation is committed after a conviction
9 of such person under this section has become final, such
10 person shall be subject to imprisonment for not more than 6
11 months, a fine of not more than \$500, or both such
12 imprisonment and fine."

13 Section 4. Section 50-31-508. MCA. is amended to read: *50-31-508. Injunction to restrain prohibited acts. In 14 15 addition to the remedies hereinafter provided, the department is hereby authorized to apply to district court 16 17 for and such court shall have jurisdiction upon hearing and 18 for cause shown to grant a temporary or permanent injunction 19 restraining any person from violating any provision of 20 50-31-204, 50-31-501, or 50-31-502, or [section 5 of this act1 irrespective of whether or not there exists an adequate 21 22 remedy at law."

23 <u>NEW SECTION</u> Section 5. Sale of hamburger and
 24 imitation hamburger. (1) No food service establishment may
 25 use the terms "hamburger", "burger", or other similar term

in any advertisement or menu to refer to any imitation hamburger. A food service establishment selling or serving imitation hamburger may refer to such product as "imitation hamburger" or by any other term which accurately informs the customer of the nature of the food product which he is sold or served.

7 (2) If imitation hamburger is sold or served in a food
 8 service establishment, a list of ingredients must appear on
 9 the menu, or, if there is no menu, on a wallboard or placard
 10 as follows:

11 (a) The ingredients must be listed in descending order 12 of predominance by weight.

13 (b) The term "imitation hamburger" or any other term 14 which accurately informs the customer of the nature of the 15 food product and its ingredients must be included, and if 16 there is no menu, such lettering on the wallboard or placard 17 must be at least 1 inch in height (72-point letters) in 18 boldface in colors that contrast with the wallboard <r 19 placard.

(c) The wallboard or planard must be posted in a
permanent place, conspicuous to the customer, in each room
or area where food is served.

Section 6. Codification. It is intended that section 5
be enacted as an integral part of chapter 31, Title 50; MCA.
and that the provisions of chapter 31. Title 50. MCA. during

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1 to section 5.

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46th Legislature

HP 0316/02

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Approved by Committee on Business and Industry

1	HOUSE BILL NO. 316
Z	INTRUDUCED BY HAND, CONROY, D'CONNELL, LIEN,
3	STAIGMILLER, JUHNSON, WOOD, KEYSER, MARKS, JOHNSTON,
4	PAVLOVICH, MCBRIDE, MANUEL, QUILICI, ROBBINS,
5	JENSEN, PISTORIA, CURTISS, GOULD, NATHE, LUND, COONEY
5	
7	A BILL FUR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE
з	ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND
9	IMITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE
rô	AND TO ADVERTISE THE LIST OF INGREDIENTS IN IMITATION
11	HAMBURGER; AND AMENDING SECTIONS 50-31-103, 50-31-312,
12	50-31-506, AND 50-31-508, MCA.*
13	

SE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA: 14 15 Section 1. Section 50-31-103. MCA, is amended to read: "50-31-103. Definitions. Unless the context requires 16 otherwise, in this chapter the following definitions apply: 17 (1) "Advertisement" means representations disseminated 18 in any manner or by any means, other than by labeling, for 19 20 the purpose of inducing or which are likely to induce. directly or indirectly, the purchase of food, drugs, 21 devices. or cosmetics. 22

23 (2) "Color" includes black, white, and intermediate 24 Jr 345+

25 (3) (a) "Color additive" means a material which:

(i) is a dye, pigment, or other substance made by a 2 process of synthesis or similar artifice or extracted, 3 isolated, or otherwise derived, with or without intermediate 4 or final change of identity, from a vegetable, animal, 5 mineral, or other source; or (ii) when added or applied to a food, drug, or cosmetic 6 7 or to the human body is capable (alone or through reaction 8 with other substance) of imparting color thereto. 9 (b) This term does not include material which has been 10 or hereafter is exempted under the federal act. 11 (4) "Consumer commodity", except as otherwise 12 specifically provided by this subsection, means any food, 13 drug, device, or cosmetic as those terms are defined by this 14 chapter or by the federal act and regulations pursuant 15 thereto. The term does not include: 16 (a) any tobacco or tobacco product; (b) a commodity subject to packaging or labeling 17 15 requirements imposed under the Federal Insecticide, 19 Fungicide, and Rodenticide Act or the provisions of the 20 eighth paragraph under the heading "Bureau of Animal 21 Industry* of the act of March 4, 1913 (37 Stat. 832-833; 21

22 U.S.C. 151-157), commonly known as the virus-serum toxin 23 act;

24 (c) a drug subject to [section 17(a)(B) or 16(k) of 25 this act] or section 503(b)(1) or 506 of the federal act:

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(d) a beverage subject to or complying with packaging
 or labeling requirements imposed under the Federal Alcohol
 Administration Act (27 U+S+C+, et seg+); or

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

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

(6) "Cosmetic" means:

10

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

15 (b) articles intended for use as a component of these16 articles, except that the term does not include soap.

17 (7) "Counterfeit drug" means a drug which, or the 18 container or labeling of which, without authorization bears 19 the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof of a drug 20 21 manufacturer, processor, packer, or distributor other than 22 the person who in fact manufactured, processed, packed, or 23 distributed the drug and which falsely purports or is represented to be the product of or to have been packed or 24 25 distributed by the other drug manufacturer, processor,

1 packer, or distributor. 2 (8) "Department" means the department of health and environmental sciences, provided for in Title 2, chapter 15, 3 4 Jart 21. (9) "Device" (except when used in 50-31-107(2), 5 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and 6 7 50-31-501(10)) means instruments, apparatus, and contrivances, including their components, parts, and R accessories, intended: 9 (a) for use in the diagnosis, cure, mitigation, 10 11 treatment, or prevention of disease in man or other animals;

17 (b) to affect the structure or function of the body of13 man or other animals.

14 (10) "Drug" means:

15 (a) articles recognized in the official United States
16 Pharmacopoeia, official Homeopathic Pharmacopoeia of the
17 United States, or official National Formulary or a
18 supplement to any 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

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not include devices or their components, parts, or

2 accessories.

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3 (11) "Federal act" means the Federal Food+ Drug+ and
4 cosmetric Act+ us amended (Title 21 U+S+C+ 301 et seq+)+

5 (12) "Food" means:

6 (u) articles used for food or drink for man or other
 7 animals;

(b) chewing gum; and

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

10 (13) (3) "Food additive" means a substance, the 11 intended use of which results or may be reasonably expected 12 to result. directly or indirectly. in its becoming a component or otherwise affecting the characteristics of food 13 (including a substance intended for use in producing. 14 manufacturing, packing, processing, preparing, treating, 15 packaging, transporting, or holding food and including a 16 17 source of radiation intended for this use), if the substance is not generally recognized, among experts qualified by 18 19 scientific training and experience to evaluate its safety. as having been adequately shown through scientific 21 procedures (or, in the case of a substance used in a food 21 22 prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be 23 24 safe under the conditions of its intended use.

25 (b) This term does not include:

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

2 commodity; (ii) a pesticide chemical to the extent that it is ٦ intended for use or is used in the production, storage, or 4 5 transportation of a raw agricultural commodity; 6 (iii) color additive; (iv) substance used in accordance with a sanction or 7 approval granted prior to the enactment of the Food A 9 Additives Amendment of 1958, pursuant to the federal act. the Poultry Products Inspection Act (21 U-S-C- 451 et seq.). 10 or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260). 11 as amended and extended (21 U.S.C. 71 et seq.). 12 13 1141 "Food service establishment" means a restaurante 14 catering vehicles vending machines delicatessens, fast-food 15 retailer, or any other place that serves food to the public

- 15 for consumption either at or away from the point of service.
- 17 and any facility operated by a governmental entity, where
- 18 food_is_served.

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19 1151_"Hamburger"___means comminuted GROUND fresh_or 20 frozen_best_or_a_combination_of_both_fresh_and_frozen_bests 21 with_or_without_the_addition_of_suet_and_with_or_without_the 22 addition_of_seasonings__if__no__fat_other__than_suets is 23 invorporated_in_the_bamburgers_the_total_fat_content_does 24 upt_exceed_203s_and__no__waters_binderss_or_extenders_are 25 added.

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1 <u>fl4y[16]</u> "Honey" means the nectar and saccharine 2 exudations of plants gathered: modified: and stored in the 3 comb by honey bees; is levorotatory: contains not more than 4 25% of water: not more than .25% of ash: and not more than 5 8% sucrose.

6 <u>117) "Imitation bamburger" means "hamburger": as</u> 7 defined in subsection <u>titt</u> <u>115): to which has been added</u> 8 binders or extenders or both binders and extenders as those 9 tarms are understood by general custom and usage in the food 10 incustry.

11 (15)(18) "Label" means a display of written, printed,
 12 or graphic matter on the immediate container of an article.
 13 ("Immediate container" does not include package liners.)

14 <u>fi6f[191</u> "Labeling" means, labels and other written, 15 printed, or graphic matter:

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

17 (b) accompanying the article.

18 [20] "Menu" means any list presented to the patron

19 which_states_the_food_items_for_sale_in_a_food_service
20 establishment.

21 <u>ti7)[21]</u> "New drug" means a drug the composition of 22 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

3 (b) the drug, as a result of investigations to 4 determine its safety and effectiveness for use under the 5 conditions prescribed, has become so recognized but which 6 has not, otherwise than in the investigations, been used to 7 a material extent or for a material time under the 8 conditions prescribed.

9 (189)[22] "Official compendium" means the official
 10 United States Pharmacopoeia, official Homeopathic
 11 Pharmacopoeia of the United States, official National
 12 Formulary, or a supplement to any of these.

13 <u>fi97[23]</u> "Package" means a container or wrapping in 14 which a consumer commodity is enclosed for use in the 15 delivery or display of that consumer commodity to retail 16 purchasers but does not include:

17 (a) shipping containers or wrappings used solely f r
18 the transportation of a consumer commodity in bulk or in
19 quantity to manufacturers, packers, or processors or to
20 wholesale or retail distributors;

(b) 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.

25 <u>{20}[24]</u> "Person" includes an individual, partnership.

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labeling with respect to such drug, which on October 9,

(a) was commercially sold or used in this state or in

(b) was not a new drug as defined by 50-31-103+17+1211

1962, or on the date immediately preceding July 1, 1967:

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ì	corporation, and association.	1	Section 2. Section 50-31-312, MCA, is amended to read:
2	<pre>f2t+1251 "Pesticide chemical" means a substance which.</pre>	Z	*50-31-312. Exemptions from new drug app≩ication
3	alone, in chemical combination, or in formulation with one	3	requirement. (1) Section 50-31-311 shall not apply to:
4	or more other substances, is an "economic poison" under the	4	(a) a drug intended solely for investigational use by
5	Federal Insecticide, Fungicide, and Rodenticide Act (7	5	experts qualified by scientific training and experience to
5	U+S+C++ secs+ 135-135k), as amended, and which is used in	6	investigate the safety and effectiveness of drugs, provided
7	the production, storage, or transportation of raw	7	the drug is plainly labeled in compliance with regulations
3	anricultural commodities.	8	issued by the department or pursuant to section 505(i) or
9	1261_"Placard"meansanynonpermanentsignused_to	9	507(d) of the federal act;
10	display or describe food items for sale in a food service	10	(b) a drug sold in this state at any time prior to the
11	establishment.	11	enactment of this chapter or introduced into interstate
12	<pre>+22+1271 "Principal display panel" means that part of a</pre>	12	commerce at any time prior to the enactment of the federal
13	lapel that is most likely to be displayed, presented, shown,	13	act;
14	or examined under normal and customary conditions of display	14	(c) any drug which is licensed under the Virus, Serum,
15	for retail sale.	15	and Toxin Act of July 1+ 1902 (U+S+C+ 1958 ed+ Title 42+
16	{≥3} <u>[28]</u> "Raw agricultural commodity" means food in its	16	chapter 6A, sec. 262); or
17	raw or natural state, including fruits that are washed.	17	(d) any drug which is subject to 50-31-306(1)(n)+
18	colored, or otherwise treated in their unpeeled natural form	18	(2) The provisions of 50-31-103 (17)[21] shall not
10	prior to marketing.	19	apply to any drug, when such drug is intended solely for use
20	t2471221 "State board" or "board" means the board of	20	under conditions prescribed, recommended, or suggested in

20 21 health and environmental sciences, provided for in 22 2-15-2104.

23 1301_"Wallboard" means any permanent sign used to display or describe food items for sale in a food service 24 25 establishment."

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the United States;

1 as then in force: and

2 (c) was not covered by an effective application under
3 50-31-311 or under section 505 of the federal act.*

Section 3. Section 50-31-506. MCA, is amended to read:
*50-31-506. Penalties. (1) Any person who violates any
of the provisions of 50-31-204. 50-31-501. or 50-31-502...or
(section 5 of this act) shall be guilty of a misdemeanor and
shall on conviction thereof be subject to imprisonment for
no: more than 3 months. a fine of not more than \$250. or
both such imprisonment and fine.

11 (2) If the violation is committed after a conviction 12 of such person under this section has become final, such 13 person shall be subject to imprisonment for not more than 6 14 months, a fine of not more, than \$500, or both such 15 imprisonment and fine."

16 Section 4. Section 50-31-508, MCA, is amended to read: 17 #50-31-508. Injunction to restrain prohibited acts. In addition to the remedies hereinafter provided, the 18 19 department is hereby authorized to apply to district court 20 for and such court shall have jurisdiction upon hearing and for cause shown to grant a temporary or permanent injunction 21 22 restraining any person from violating any provision of 23 50-31-204, 50-31-501, or 50-31-502, or [section 5. of this 24 act] irrespective of whether or not there exists an adequate remedy at law." 25

NEW SECTION. Section 5. Sale of hamburger and 1 imitation hamburger. (1) No food service establishment may 2 use the terms "homburger", "burger", or other similar term 3 in any advertisement or menu to refer to any imitation 4 hamburger. A food service establishment selling or serving 5 imitation hamburger may refer to such IHE product as 6 "imitation hamburger" or by any other term which accurately 7 informs the customer of the nature of the food product which 8 Q he is sold or served. (2) If imitation hamburger is sold or served in a food 10 service establishment, a list of ingredients must appear on 11 the menu, or, if there is no menu, on a wallboard or placard 12 13 as follows: tat--The-ingredients-must-be-listed-in-descending-order 14 of-predominance-by-weightw 15 (b)(A) The term "imitation hamburger" or any other 16 term which accurately informs the customer of the nature of 17 the food product and its ingredients must be includedy_ and 18 (8) INE INGREDIENTS MUST BE LISTED IN DESCENDING ORDER 19 OF PREDOMINANCE BY WEIGHT. 20 (C) if IE there is no menu, such IHE lettering on the 21 22 wallboard or placard must be at least 1 inch in height (72-point letters) in boldface AND in colors that contrast 23 with the wallboard or placard. 24 fcf(D) The wallboard or placard must be posted in a 25

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µermanent place, conspicuous to the customer, in each room
 or area where food is served.
 Section 6. Codification. It is intended that section 5
 be enacted as an integral part of chapter 31. Title 50, MCA,
 and that the provisions of chapter 31. Title 50, MCA, apply
 to section 5.

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HOUSE BILL NO. 316 INTRODUCED BY HAND, CONROY, O'CONNELL, LIEN, IGMILLER, JUHNSON, WOOD, KEYSER, MARKS, JOHNSTON, PAVLOVICH, MCBRIDE, MANUEL, QUILICI, ROBBINS, EN, PISTORIA, CURTISS, GOULD, NATHE, LUND, COONEY	1 2 3 4 5 6	(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
IGMILLER, JUHNSON, WOOD, KEYSER, MARKS, JOHNSTON, Pavlovich, McBride, Manuel, Quilici, Robbins,	3 4 5	isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal,
PAVEOVICH, MCBRIDE, MANUEL, QUILICI, ROBBINS,	4	or final change of identity, from a vegetable, animal,
	5	
EN, PISTORIA, CURTISS, GOULD, NATHE, LUND, COONEY		mineral, or other source; or
	6	
	Ų	(ii) when added or applied to a food+ drug+ or cosmetic
FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE	7	or to the human body is capable (alone or through reaction
SHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND	8	with other substance) of imparting color thereto.
ON HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE	9	(b) This term does not include material which has been
ADVERTISE THE LIST OF INGREDIENTS IN INITATION	10	or hereafter is exempted under the federal act.
ER; AND AMENDING SECTIONS 50-31-103, 50-31-312.	11	(4) "Consumer commodity", except as otherwise
06, AND 50-31-508, HCA.*	12	specifically provided by this subsection, means any food,
	13	drug, device, or cosmetic as those terms are defined by this
NACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:	14	chapter or by the federal act and regulations pursuant
ction 1. Section 50-31-103. HCA. is amended to read:	15	thereto. The term does not include:
0-31-103. Definitions. Unless the context requires	16	(a) any tobacco or tobacco product;
se, in this chapter the following definitions apply:	17	(b) a commodity subject to packaging or labeling
) "Advertisement" means representations disseminated	19	requirements imposed under the Federal Insecticide,
manner or by any means, other than by labeling, for	19	Fungicide, and Rodenticide Act or the provisions of the
rpose of inducing or which are likely to induce.	20	aighth parayraph under the heading "Bureau of Animal
y or indirectly, the purchase of food, drugs,	21	Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21
• or cosmetics•	22	U.S.C. 151-157), commonly known as the virus-serum toxin
) "Color" includes black, white, and intermediate	23	act;
	24	(c) a drug subject to [section 17(a)(B) or 16(k) of
	25	this act] or section 503(b)(1) or 506 of the federal act;
)	or indirectly, the purchase of food, drugs, or cosmetics.	or indirectly, the purchase of food, drugs, 21 or cosmetics. 22) *Color* includes black, white, and intermediate 23 24

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(d) a beverage subject to or complying with packaging
 or labeling requirements imposed under the Federal Alcohol
 Administration Act (27 U+S+C++ et seg+); or

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

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

10 (6) "Cosmetic" means:

11 (a) articles intended to be rubbed, poured, sprinkled, 12 sprayed on, introduced into, or otherwise applied to the 13 human body for cleansing, beautifying, promoting 14 attractiveness, or altering the appearance;

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

17 (7) "Counterfeit drug" means a drug which, or the 18 container or labeling of which, without authorization bears 19 the trademark, trade name, or other identifying mark, 20 imprint, or device or any likeness thereof of a drug 21 manufacturer, processor, packer, or distributor other than 22 the person who in fact manufactured, processed, packed, or 23 distributed the drug and which falsely purports or is represented to be the product of or to have been packed or 24 25 distributed by the other drug manufacturer, processor,

1 packer. or distributor. (8) "Department" means the department of health and 2 environmental sciences, provided for in Title 2, chapter 15, 3 part 21. 4 (9) "Device" (except when used in 50-31-107(2), 5 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and 6 7 50-31-501(10)) means instruments. apparatus. and contrivances, including their components, parts, and 8 9 accessories+ intended: 10 (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; 11 12 (b) to affect the structure or function of the body of 13 man or other animals. 14 (10) "Orug" means: 15 (a) articles recognized in the official United States 16 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary or -17 18 supplement to any of these; 19 (b) articles intended for use in the diagnosis, cure, 20 mitigation, treatment, or prevention of disease in man or 21 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 the

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not include devices or their components, parts, or
 accessories.

3 (11) "Federal act" means the Federal Food. Drug. and
4 Cosmetric Act. as amended (Title 21 U.S.C. 301 et seq.).

5 (12) "Food" means:

6 (a) articles used for food or drink for man or other
 7 animals:

(b) chewing gum; and

8

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

(13) (a) "Food additive" means a substance, the 10 intended use of which results or may be reasonably expected 11 to result, directly or indirectly, in its becoming a 12 component or otherwise affecting the characteristics of food 13 (including a substance intended for use in producing, . 4 manufacturing, packing, processing, preparing, treating, 15 packaging, transporting, or holding food and including a 16 source of radiation intended for this use). if the substance 17 is not generally recognized, among experts qualified by 18 scientific training and experience to evaluate its safety. 19 as having been adequately shown through scientific 20 procedures (or, in the case of a substance used in a food 21 prior to January 1, 1958, through either scientific 22 procedures or experience based on common use in food) to be 23 safe under the conditions of its intended use. 24

25 (b) This term does not include:

1 (i) a pesticide chemical in or on a raw agricultural 2 commodity;

3 (ii) a posticide chemical to the extent that it is
4 intended for use or is used in the production, storage, or
5 transportation of a raw agricultural commodity;

(iii) color additive;

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7 (iv) substance used in accordance with a sanction or 8 approval granted prior to the enactment of the Food 9 Additives Amendment of 1958, pursuant to the federal act, 10 the Poultry Products Inspection Act (21 U-S-C- 451 et seq.), 11 or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), 12 as amended and extended (21 U-S-C- 71 et seq.).

13 <u>[14] "Food_service_establishment" means a restaurants</u>

14 <u>catering_vehicles_vending_machines_delicatessens_fast=food</u>

- 15 retailers or any other place that serves food to the public
 - for consumption either at or sway from the point of services
- 17 and any facility operated by a governmental entity where
- 18 food is served.
- 19 (15) "Homburger" means comminuted GROUND fresh or
- 20 frozen beef or a combination of both fresh and frozen beef:
- 21 with or without the addition of sucts and with or without
- 22 the addition of seasoning. if no fat other than suct is
- 23 incorporated in the hashurger, the total fat content does
- 24 not exceed 20% and no water. binders. or extenders are 25 added.

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Ł f14)[16] "Honey" means the nectar and saccharine 2 exudations of plants gathered, modified, and stored in the comb by honey bees; is leverotatory, contains not more than 3 25% of water, not more than .25% of ash, and not more than 4 8% sucrose. 5

6 1171_"Imitation_hamburger"___means___hamburger":___as 7 defined in subsection fift (151, to which has been added 8 binders or extenders or both binders and extenders as those a terms are understood by general custom and usage in the food 10 industry

11 (15)(18) "Label" means a display of written, printed. or graphic matter on the immediate container of an article. 12 ("Immediate container" does not include package liners.) 13

fid;[19] "Labeling" means labels and other written. 14 15 printed, or graphic matter:

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

17 (b) accompanying the article.

18 (20) "Henu" means any list presented to the patron

which states the food items for sale in a food service 19 20 establishment.

21 f27)[21] "New drug" means a drug the composition of 22 which is such that:

23 (a) it is not generally recognized, among experts qualified by scientific training and experience to evaluate 24 25 the safety and effectiveness of drugs, as safe and effective

for use under the conditions prescribed, recommended, or ł 2 suggested in its labeling; or (b) the drug, as a result of investigations to 3 determine its safety and effectiveness for use under the

conditions prescribed, has become so recognized but which has not, otherwise than in the investigations, been used to 6 a material extent or for a material time under the 7 8 conditions prescribed.

(18)(22) "Official compendium" means the official 9 10 United States Pharmacopoeia. official Homeopathic 11 Pharmacopoela of the United States, official National Formulary, or a supplement to any of these. 12

f191(23) "Package" means a container or wrapping in 13 which a consumer commodity is enclosed for use in the 14 delivery or display of that consumer commodity to retail 15 purchasers but does not include: 16

(a) shipping containers or wrappings used solely for 17 the transportation of a consumer commodity in bulk or in 18 19 quantity to manufacturers, packers, or processors or to 20 wholesale or retail distributors;

21 (b) shipping containers or outer wrappings used by retailers to ship or deliver a commodity to retail customers 22 23 if the containers and wrappings bear no printed matter 24 pertaining to a particular commodity.

25 (20)(24) "Person" includes an individual. Dartnership.

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1 corporation, and association.

2 <u>titt(25)</u> "Pesticide chemical" means a substance which, 3 alone, in chemical combination, or in formulation with one 4 or more other substances, is an "economic poison" under the 5 Federal Insecticide, Fungicide, and Rodenticide Act (7 6 U.S.C., secs. 135-135k), as amended, and which is used in 7 the production, storage, or transportation of raw 8 agricultural commodities.

<u>1261 "Placard" means any nonpermanent sign used to</u>
 <u>display or describe food items for sale in a food service</u>
 <u>establishment</u>

12 <u>t22<u>t1271</u> "Principal display panel" means that part of a 13 label that is most likely to be displayed, presented, shown. 14 or examined under normal and customary conditions of display 15 for retail sale.</u>

16 (±3)(28) "Raw agricultural commodity" means food in its 17 raw or natural state, including fruits that are washed. 18 colored, or otherwise treated in their unpeeled natural form 19 prior to marketing.

20 <u>tr4j[22]</u> "State board" or "board" means the board of 21 health and environmental sciences, provided for in 22 2-15-2104.

23 (30)_"Wallboard"__means__any__permanent__sign_used_to
 24 display_or_describe_food_items_for_sale_in_a_food_service
 25 establishment_"

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Section 2. 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:

4 (a) a drug intended solely for investigational use by 5 experts qualified by scientific training and experience to 6 investigate the safety and effectiveness of drugs, provided 7 the drug is plainly labeled in compliance with regulations 8 issued by the department or pursuant to section 505(i) or 9 507(d) of the federal act;

10 (b) a drug sold in this state at any time prior to the 11 enactment of this chapter or introduced into interstate 12 commerce at any time prior to the enactment of the federal 13 act;

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

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

(2) The provisions of 50-31-103+17+(21) shall not
apply to any drug, when such drug is intended solely for use
under conditions prescribed, recommended, or suggested in
labeling with respect to such drug, which 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;

25 (b) was not a new drug as defined by 50-31-103(117)(21)

1 as then in force; and

2 (c) was not covered by an effective application under
 3 50-31-311 or under section 505 of the federal act.*

Section 3. Section 50-31-506, MCA, is amended to read:
*50-31-506. Penalties. (1) Any person who violates any
of the provisions of 50-31-204. 50-31-501. or 50-31-502. or
<u>Isoction 5 of this act</u> shall be guilty of a misdemeanor and
shall on conviction thereof be subject to imprisonment for
not more than 3 months. a fine of not more than \$250. or
both such imprisonment and fine.

11 (2) If the violation is committed after a conviction 12 of such person under this section has become final, such 13 person shall be subject to imprisonment for not more than 6 14 months, a fine of not more than \$500, or both such 15 imprisonment and fine."

16 Section 4. Section 50-31-508, MCA, is amended to read: 17 "50-31-508. Injunction to restrain prohibited acts. In 18 addition to the remedies hereinafter provided, the 19 department is hereby authorized to apply to district court 20 for and such court shall have jurisdiction upon hearing and 21 for cause shown to grant a temporary or permanent injunction 22 restraining any person from violating any provision of 23 50-31-204, 50-31-501, or 50-31-502, or [section 5 of this 24 act] irrespective of whether or not there exists an adequate 25 remedy at law."

NEW_SECTION. Section 5. Sale of hamburyer and 1 imitation hamburger. (1) No food service establishment may 2 use the terms "hamburger", "burger", or other similar term 2 in any advertisement or menu to refer to any imitation 4 hamburger. A food service establishment selling or serving 5 imitation hamburger may refer to such <u>THE</u> product as 6 "imitation hamburger" or by any other term which accurately 7 informs the customer of the nature of the food product which R he is sold or served. 0

10 (2) If imitation hamburger is sold or served in a food
11 service establishment, a list of ingredients must appear on
12 the menu, or, if there is no menu, on a wallboard or placard
13 as follows:

14 fat--The-ingredients-must-be-iisted-in-descending-order
15 of-predominance-by-weights
16 (b)(A) The term "imitation hamburger" or any other

term which accurately informs the customer of the nature of 17 18 the food product and its ingredients must be included and (a) THE INGREDIENTS MUST BE LISTED IN DESCENDING DRDER 19 DE PREDOMINANCE_BY_WEIGHT. 20 (C) if IE there is no menu, such IHE lettering on the 21 22 wallboard or placard must be at least 1 inch in height (72-point letters) in boldface AND in colors that contrast 23 with the wallboard or placard. 24

25 tet<u>fDi</u> The wallboard or placard must be posted as a

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permanent place, conspicuous to the customer, in each room
 or area where food is served.
 Section 6. Codification. It is intended that section 5
 be enacted as an integral part of chapter 31, Title 50, MCA,
 and that the provisions of chapter 31, Title 50, MCA, apply
 to section 5.

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1	HOUSE BILL NO. 316	1	(i) is a dye, pigment, or other substance made by a
,	INTRODUCED BY HAND, CONROY, O'CONNELL, LIEN,	?	process of synthesis or similar artifice or extracted.
3	STAIGMILLER, JOHNSON, WOOD, KEYSER, MARKS, JOHNSTON,	3	isolated, or otherwise derived, with or without intermediate
4	PAVLUVICH, MCBRIDE, MANUEL, QUILICI, K. ROBBINS,	4	or final change of identity, from a vegetable, animal,
5	JENSEN+ PISTORIA+ CURTISS+ GOULD+ NATHE+ LUND+ COONEY	5	mineral, or other source; or
6		ڹ	(ii) which added or applicat to a fundy drugy or cosmetic
7	A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE	7	or to the human body is capable (alone or through reaction
8	ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND	8	with other substance) of imparting color thereto.
9	IMITATION HAHBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE	9	(b) This term does not include material which has been
10	AND TO ADVERTISE THE LIST OF INGREDIENTS IN IMITATION	10	or hereafter is exempted under the federal act.
11	HAMBURGER; AND AMENDING SECTIONS 50-31-103, 50-31-312,	11	(4) "Consumer commodity", except as otherwise
12	50-31-506, AND 50-31-508, MCA."	12	specifically provided by this subsection, means any food,
13		13	drug, device, or cosmetic as those terms are defined by this
14	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:	14	chapter or by the federal act and regulations pursuant
15	Section 1. Section 50-31-103, MCA, is amended to read:	15	thereto. The term does not include:
16	#50-31-103. Definitions. Unless the context requires	15	(a) any tobacco or tobacco product;
17	otherwise: in this chapter the following definitions apply:	17	(b) a commosity subject to packaging or labeling
18	(1) "Advertisement" means representations disseminated	18	requirements imposed under the Federal Insecticide:
19	in any manner or by any means, other than by labeling, for	19	Fungicide+ and Rodenticide Act or the provisions of the
20	the purpose of inducing or which are likely to induce.	20	eighth paragraph under the heading "Bureau of Animal
21	directly or indirectly, the purchase of food, drugs,	21	Industry" of the act of March 4+ 1913 (37 Stat+ 832-833; 21
22	devices, or cosmetics.	22	U+S+C+ 151-157)+ commonly known as the virus-serum toxin
23	(2) "Color" includes black: white: and intermediate	23	act;
24	grays.	24	{c} a drug subject to [section 17(a)(B) or 16(k) of
25	(3) (a) "Color additive" means a material which:	25	this act] or section 503(b)(1) or 506 of the federal act;
			•
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(d) a beverage subject to or complying with packaging
 or labeling requirements imposed under the Federal Alcohol

3 Administration Act (27 U+S+C++ et seq+); or

4 (e) a commodity subject to the Federal Seed Act (7
5 U+S+C+ 1551-1610)+

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

10 (6) *Cosmetic* means:

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

17 (?) Counterfait drug# means of from which, or the 18 container or labeling of which, without authorization bears 19 the trademark, trade name, or other identifying mark, 20 imprint, or device or any likeness thereof of a drug manufacturer, processor, packer, or distributor other than 21 the person who in fact manufactured, processed, packed, or 22 23 distributed the drug and which falsely purports or is 24 represented to be the product of or to have been packed or 25 distributed by the other drug manufacturer, processor, 1 packer, or distributor. 2 (8) "Department" means the department of health and 3 environmental sciences, provided for in Title 2, chapter 15, part 21. 4 5 (9) "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 6 7 50-31-501(10)} means instruments. apparatus. and contrivances, including their components, parts, and 8 9 accessories, intended:

10 (a) for use in the diagnosis, cure, mitigation,
11 treatment, or prevention of disease in man or other animals;
12 (b) to affect the structure or function of the body of
13 man or other animals.

14 (10) "Drug" means:

15 (a) articles recognized in the official United States 16 Pharmacopoela, official Homeopathic Pharmacopoela of the 17 United States, or official National Formulary or a 18 supplement to any 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

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1 not include devices or their components, parts, or 2 accessories.

3 (11) "Federal act" means the Federal Food, Drug, and
4 Cosmetic Act, as amended (Title 21 U.S.C. 301 et seq.).

5 (12) "Food" means:

6 (a) articles used for food or drink for man or other 7 animals;

B (b) chewing gum; and

(c) articles used for components of these articles. 9 10 (13) (a) "Food additive" means a substance, the intended use of which results or may be reasonably expected 11 12 to result. directly or indirectly, in its becoming a 13 component or otherwise affecting the characteristics of food 14 (including a substance intended for use in producing, 15 manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and including a 16 17 source of radiation intended for this use), if the substance 18 is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety. 19 20 as having been adequately shown through scientific procedures (or, in the case of a substance used in a food 21 prior to January 1, 1958, through either scientific 22 procedures or experience based on common use in food) to be 23 24 safe under the conditions of its intended use.

25 (b) This term does not include:

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1 (i) a pesticide chemical in or on a raw agricultural 2 commodity;

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

(iii) color additive;

6

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

13 (14) "Food service establishment" means a restaurant: catering vehicles vending machines delicatessens fast-food 14 15 retailers or any other place that serves food to the public 16 for consumption either at or away from the point of services 17 and any facility operated by a governmental entity where 13 food_is_served. (15) "Hamburger" _____ means comminated GROUND fresh_or 19 20 frozen beef or a combination of both fresh and frozen beef. 21 with or without the addition of suct: and with or without

22 the addition of seasonings if no fat other than suct is

23 incorporated__in_the__bamburgers_the_total_fat_content_does
 24 not_exceed_20%s_and_no__waters__binderss_or__extenders__are
 25 addeds

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1 (14)(16) "Honey" means the nectar and saccharine 2 exudations of plants gathered, modified, and stored in the 3 comb by honey bees; is levorotatory, contains not more than 4 25% of water, not more than .25% of ash, and not more than 5 8% sucrose.

6 <u>1171_"Imitation__hamburger"__means___"hamburger"._as</u> 7 <u>defined_in_subsection fift 1151.to_which_bas_been_added</u> 8 <u>binders_or_extenders_or_both_binders_and_extenders_as_those</u> 9 <u>terms_are_understood_by_general_custom_and_usage_in_the_food</u> 10 <u>industrys</u>

tts;[10] "Label" means a display of written. printed.
 or graphic matter on the immediate container of an article.
 ("Immediate container" does not include package liners.)

14 (16)(19) "Labeling" means labels and other written.
15 printed, or graphic matter:

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

17 (b) accompanying the orticle.

18 <u>1201_"Henu"_means_any_list_presented_to_the_patron</u>
19 which_states_the_food_items__for__sale__in__a__food__service
20 establishment_

21 <u>ti7f(21)</u> "New drug" means a drug the composition of 22 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

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for use under the conditions prescribed, recommended, or
 suggested in its labeling; or

3 (b) the drug, as a result of investigations to 4 determine its safety and effectiveness for use under the 5 conditions prescribed, has become so recognized but which 6 has not, otherwise than in the investigations, been used to 7 a material extent or for a material time under the 8 conditions prescribed.

9 <u>ti0†1221</u> "Official compendium" means the official
10 United States Pharmacopoeia, official Homeopathic
11 Pharmacopoeia of the United States, official National
12 Formulary, or a supplement to any of these.

13 <u>(19)(231</u> "Package" means a container or wrapping in 14 which a consumer commodity is enclosed for use in the 15 delivery or display of that consumer commodity to retail 16 purchasers but does not include:

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

(b) 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.

25 f201(24) "Person" includes an individual, partnership.

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1	corporation, and association.	1	Section 2. Section 50-31-312, MCA, is amended to read:
2	<pre>f2ty1251 "Pesticide chemical" means a substance which.</pre>	2	#50-31-312. Exemptions from new drug application
3	alone, in chemical combination, or in formulation with one	3	requirement. (1) Section 50-31-311 shall not apply to:
4	or more other substances, is an "economic poison" under the	4	(a) a drug intended solely for investigational use by
5	Federal Insecticide, Fungicide, and Rodenticide Act (7	5	experts qualified by scientific training and experience to
6	U.S.C., secs. 135-135k), as amended, and which is used in	6	investigate the safety and effectiveness of uragey $(p(z, z))^{-1}$
г	the production, storage, or transportation of raw	7	the drug is plainly labeled in compliance with regulations
8	agricultural commodities.	8	issued by the department or pursuant to section 505(i) or
9	(26) "Placard" means any nonpermanent sign used to	9	507(d) of the federal act;
10	display_ordescribefood_items_for_sale_in_a_food_service	10	(b) a drug sold in this state at any time prior to the
11	establishmenta	11	enactment of this chapter or introduced into interstate
12	<pre>t22;1271 "Principal display panel" means that part of a</pre>	12	commerce at any time prior to the enactment of the federal
13	label that is most likely to be displayed, presented, shown,	13	act;
14	or examined under normal and customary conditions of display	14	(c) any drug which is licensed under the Virus, Serum,
15	for retail sale.	15	and Toxin Act of July 1+ 1902 (U+S+C+ 1958 ed+ Title 42+
16	<pre>f23f1281 "Raw agricultural commodity" means food in its</pre>	16	chapter 6A. sec. 262]; or
17	raw or natural state, including fruits that are washed,	17	(d) any drug which is subject to 50-31-306(1)(n).
18	colored, or otherwise treated in their unpeeled natural form	18	(2) The provisions of 50-31-103+27+1211 shall not
19	prior to marketing.	19	apply to any drug, when such drug is intended solely for use
20	[24][29] "State board" or "board" means the board of	20	under conditions prescribed, recommended, or suggested in
21	health and environmental sciences+ provided for in	21	labeling with respect to such drug, which on October 9,
22	2-15-2104.	22	1962, or on the date immediately preceding July 1, 1967:
23	[30]_"Wallboard"meansanypermanentsignusedto	23	(a) was commercially sold or used in this state or in
24	display_or_describe_food_ltems_for_sale_ina_food_service	24	the United States;
25	establishment."	25	(b) was not a new drug as defined by 50-31-103 (17)[21]
	• · · · · · · · · · · · · · · · · · · ·		
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1 as then in force; and

2 (c) was not covered by an effective application under
3 50-31-311 or under section 505 of the federal act.^a
4 Section 3. Section 50-31-506. MCA, is amended to read:
5 "50-31-506. Penalties. (1) Any person who violates any

of the provisions of 50-31-204, 50-31-501, or 50-31-502<u>, or</u>
<u>(suction 5 of this act)</u> shall be quilty of a misdemeanor and
shall on conviction thereof be subject to imprisonment for
not more than 3 months, a fine of not more than \$250, or
both such imprisonment and fine.

11 (2) If the violation is committed after a conviction 12 of such person under this section has become final, such 13 person shall be subject to imprisonment for not more than 6 14 months, a fine of not more than \$500, or both such 15 imprisonment and fine."

Section 4. Section 50-31-508, MCA, is amended to read: 16 #50-31-508. In parchism to restrain prohibited acts. In 17 addition to the remedies hereinafter provided, the 16 19 department is hereby authorized to apply to district court 20 for and such court shall have jurisdiction upon hearing and for cause shown to grant a temporary or permanent injunction 21 22 restraining any person from violating any provision of 50-31-204, 50-31-501, or 50-31-502, or [section_5_of_this 23 act] irrespective of whether or not there exists an adequate 24 remedy at law." 25

1 NEW_SECTION, Section 5. Sale of hamburger and 2 imitation hamburger. (1) No food service establishment may use the terms "hamburger", "burger", or other similar term з in any advertisement or menu to refer to any imitation 5 hamburger. A food service establishment selling or serving 6 imitation hamburger may refer to such INE product as "imitation hamburger" or by any other term which accurately 7 8 informs the customer of the nature of the food product which 9 he is sold or served. 10 (2) If imitation hamburger is sold or served in a food 11 service establishment, a list of ingredients must appear on 12 the menu, or, if there is no menu, on a wallboard or placard 13 as follows:

14 ta;--The-ingradients-must-be-fisted-in-descending-order

15 of-predominance-by-weights

16 fb)(A) The term "imitation hamburger" or any other 17 term which accurately informs the customer of the nature of 18 the food product and its ingredients must be includedy, and (B) THE INGREDIENTS MUST BE LISTED IN DESCENDING ORDER 19 20 OF_PREDOMINANCE_BY_WEIGHT. 21 (L) if LE there is no menu; such IHE lettering on the 22 wallboard or placard must be at least 1 inch in height (72-point letters) in boldface AND in colors that contrast 23 with the wallboard or placard. 24

25 tet<u>[D]</u> The wallboard or placard must be posted in a

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- 1 permanent place, conspicuous to the customer, in each room
- 2 or area where food is served.
- 3 Section 6. Codification. It is intended that section 5
- 4 be enacted as an integral part of chapter 31, Title 50, MCA,
- 5 and that the provisions of chapter 31, Title 50, MCA, apply
- 6 to section 5.

-End-