

## 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 Committee 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.

HOUSE BILL NO. 316

*Ritter*  
*Allyson*  
*Sold*  
*NATHAN*  
*Frank*  
*Conroy*

INTRODUCED BY *Mark Conroy* *O'Connell* *Lin*

A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE

ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND  
IMITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE  
AND TO ADVERTISE THE LIST OF INGREDIENTS IN IMITATION  
HAMBURGER; AND AMENDING SECTIONS 50-31-103, 50-31-312,  
50-31-506, AND 50-31-508, MCA."

*John*  
*Michael*  
*Manuel*  
*John*  
*Rollins*  
*James*

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

(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

(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.

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

(a) any tobacco or tobacco product;

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

(c) a drug subject to [section 17(a)(8) or 16(k) of this act] or section 503(b)(1) or 506 of the federal act;

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

1 (e) a commodity subject to the Federal Seed Act (7  
2 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.

7 (6) "Cosmetic" means:

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 these  
13 articles, except that the term does not include soap.

14 (7) "Counterfeit drug" means a drug which, or the  
15 container or labeling of which, without authorization bears  
16 the trademark, trade name, or other identifying mark,  
17 imprint, or device or any likeness thereof of a drug  
18 manufacturer, processor, packer, or distributor other than  
19 the person who in fact manufactured, processed, packed, or  
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,  
8 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) "Drug" 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

1 Cosmetic Act, as amended (Title 21 U.S.C. 301 et seq.).

2 (12) "Food" means:

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

5 (b) chewing gum; and

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

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

22 (b) This term does not include:

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

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

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

3 (iii) color additive;

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

10 (14) "Food service establishment" means a restaurant,  
11 catering vehicle, vending machine, delicatessen, fast-food  
12 retailer, or any other place that serves food to the public  
13 for consumption either at or away from the point of service,  
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 beef, with or  
18 without the addition of suet and with or without the  
19 addition of seasoning, if no fat other than suet is  
20 incorporated in the hamburger, the total fat content does  
21 not exceed 20% and no water, binders, or extenders are  
22 added.

23 ~~(14)~~(16) "Honey" means the nectar and saccharine  
24 exudations of plants gathered, modified, and stored in the  
25 comb by honey bees; is levorotatory, contains not more than

1 25% of water, not more than .25% of ash, and not more than  
2 8% sucrose.

3 ~~(17) "Imitation hamburger" 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 ~~industry.~~

8 ~~(15)(18) "Label" means a display of written, printed,~~  
9 ~~or graphic matter on the immediate container of an article.~~  
10 ~~("Immediate container" does not include package liners.)~~

11 ~~(16)(19) "Labeling" means labels and other written,~~  
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 ~~establishment.~~

18 ~~(17)(21) "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  
22 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

1 determine its safety and effectiveness for use under the  
2 conditions prescribed, has become so recognized but which  
3 has not, otherwise than in the investigations, been used to  
4 a material extent or for a material time under the  
5 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 ~~(19)(23) "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 by  
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.

22 ~~(20)(24) "Person" includes an individual, partnership,~~  
23 ~~corporation, and association.~~

24 ~~(21)(25) "Pesticide chemical" means a substance which,~~  
25 ~~alone, in chemical combination, or in formulation with one~~

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

6 ~~(26) "Placard" means any nonpermanent sign used to~~  
 7 ~~display or describe food items for sale in a food service~~  
 8 ~~establishment.~~

9 ~~(22)(27)~~ "Principal display panel" means that part of a  
 10 label that is most likely to be displayed, presented, shown,  
 11 or examined under normal and customary conditions of display  
 12 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) "Wallboard" 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:

1 (a) a drug intended solely for investigational use by  
 2 experts qualified by scientific training and experience to  
 3 investigate the safety and effectiveness of drugs, provided  
 4 the drug is plainly labeled in compliance with regulations  
 5 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;

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

1 Section 3. Section 50-31-506, MCA, is amended to read:  
 2 "50-31-506. Penalties. (1) Any person who violates any  
 3 of the provisions of 50-31-204, 50-31-501, or 50-31-502, or  
 4 [section 5 of this act] shall be guilty of a misdemeanor and  
 5 shall on conviction thereof be subject to imprisonment for  
 6 not more than 3 months, a fine of not more than \$250, or  
 7 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:  
 14 "50-31-508. Injunction to restrain prohibited acts. In  
 15 addition to the remedies hereinafter provided, the  
 16 department is hereby authorized to apply to district court  
 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  
 21 act] irrespective of whether or not there exists an adequate  
 22 remedy at law."

23 NEW SECTION. 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

1 in any advertisement or menu to refer to any imitation  
 2 hamburger. A food service establishment selling or serving  
 3 imitation hamburger may refer to such product as "imitation  
 4 hamburger" or by any other term which accurately informs the  
 5 customer of the nature of the food product which he is sold  
 6 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 or  
 19 placard.

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

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



LC 0367/01

1 to section 5.

-End-

HB 316

Approved by Committee  
on Business and Industry

1 HOUSE BILL NO. 316  
2 INTRODUCED BY HAND, CONROY, O'CONNELL, LIEN,  
3 STAIGMILLER, JOHNSON, WOOD, KEYSER, MARKS, JOHNSTON,  
4 PAVLOVICH, MCBRIDE, MANUEL, QUILICI, ROBBINS,  
5 JENSEN, PISTORIA, CURTISS, GOULD, NATHE, LUND, COONEY  
6

7 A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE  
8 ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND  
9 IMITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE  
10 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

14 IF ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

15 Section 1. Section 50-31-103, MCA, is amended to read:  
16 "50-31-103. Definitions. Unless the context requires  
17 otherwise, in this chapter the following definitions apply:

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

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

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

1 (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

6 (ii) when added or applied to a food, drug, or cosmetic  
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;

17 (b) a commodity subject to packaging or labeling  
18 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;

1 (d) a beverage subject to or complying with packaging  
 2 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:  
 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;  
 15 (b) articles intended for use as a component of these  
 16 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  
 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,  
 4 part 21.  
 5 (9) "Device" (except when used in 50-31-107(2),  
 6 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
 7 50-31-501(10)) means instruments, apparatus, and  
 8 contrivances, including their components, parts, and  
 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 Pharmacopoeia, official Homeopathic Pharmacopoeia of the  
 17 United States, or official National Formulary or a  
 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;  
 22 (c) articles (other than food) intended to affect the  
 23 structure or function of the body of man or other animals;  
 24 (d) articles intended for use as components of any  
 25 article specified in subsections (a), (b), or (c), but does

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;

8 (b) chewing gum; and

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

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

25 (b) This term does not include:

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;

6 (iii) color additive;

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,~~  
14 ~~catering vehicle, vending machine, delicatessen, fast-food~~  
15 ~~retailer, or any other place that serves food to the public~~  
16 ~~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.~~

19 (15) "Hamburger" means comminuted GROUND fresh or  
20 frozen beef or a combination of both fresh and frozen beef,  
21 with or without the addition of suet and with or without the  
22 addition of seasoning, if no fat other than suet is  
23 incorporated in the hamburger, the total fat content does  
24 not exceed 20% and no water, binders, or extenders are  
25 added.

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        ~~†17†~~ "Imitation hamburger" means "hamburger", as  
 7 defined in subsection ~~†14†~~ †15†, to which has been added  
 8 binders or extenders or both binders and extenders as those  
 9 terms are understood by general custom and usage in the food  
 10 industry.

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        ~~†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 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        ~~†17†~~†21† "New drug" means a drug the composition of  
 22 which is such that:

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

1 for use under the conditions prescribed, recommended, or  
 2 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        ~~†18†~~†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        ~~†19†~~†23† "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  
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 22 retailers to ship or deliver a commodity to retail customers  
 23 if the containers and wrappings bear no printed matter  
 24 pertaining to a particular commodity.

25        ~~†20†~~†24† "Person" includes an individual, partnership,

1 corporation, and association.

2 ~~{21}~~{25} "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.

9 ~~{26}~~ "Placard" means any nonpermanent sign used to  
10 display or describe food items for sale in a food service  
11 establishment.

12 ~~{22}~~{27} "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.

16 ~~{23}~~{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 ~~{24}~~{29} "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."

1 Section 2. Section 50-31-312, MCA, is amended to read:

2 "50-31-312. Exemptions from new drug application  
3 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).

18 (2) The provisions of 50-31-103~~{17}~~{21} shall not  
19 apply to any drug, when such drug is intended solely for use  
20 under conditions prescribed, recommended, or suggested in  
21 labeling with respect to such drug, which on October 9,  
22 1962, or on the date immediately preceding July 1, 1967:

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

25 (b) was not a new drug as defined by 50-31-103~~{17}~~{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."

4 Section 3. Section 50-31-506, MCA, is amended to read:

5 "50-31-506. Penalties. (1) Any person who violates any  
6 of the provisions of 50-31-204, 50-31-501, or 50-31-502, or  
7 [section 5 of this act] shall be guilty of a misdemeanor and  
8 shall on conviction thereof be subject to imprisonment for  
9 not more than 3 months, a fine of not more than \$250, or  
10 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."

1 NEW SECTION. Section 5. Sale of hamburger and  
2 imitation hamburger. (1) No food service establishment may  
3 use the terms "hamburger", "burger", or other similar term  
4 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 THE product as  
7 "imitation hamburger" or by any other term which accurately  
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 ~~(a) The ingredients must be listed in descending order~~  
15 ~~of predominance by weight.~~

16 (b) ~~(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 included, and

19 (B) THE INGREDIENTS MUST BE LISTED IN DESCENDING ORDER  
20 OF PREDOMINANCE BY WEIGHT.

21 (c) ~~if~~ IF there is no menu, such THE lettering on the  
22 wallboard or placard must be at least 1 inch in height  
23 (72-point letters) in boldface AND in colors that contrast  
24 with the wallboard or placard.

25 ~~(d)~~ (D) The wallboard or placard must be posted in a

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-



## HOUSE BILL NO. 316

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

A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE  
 ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND  
 IMITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE  
 AND TO ADVERTISE THE LIST OF INGREDIENTS IN IMITATION  
 HAMBURGER; AND AMENDING SECTIONS 50-31-103, 50-31-312,  
 50-31-506, AND 50-31-508, 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) "Color" includes black, white, and intermediate  
 grays.

(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

(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.

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

(a) any tobacco or tobacco product;

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

(c) a drug subject to [section 17(a)(8) or 16(k) of  
 this act] or section 503(b)(1) or 506 of the federal act;

1 (d) a beverage subject to or complying with packaging  
 2 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:

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;

15 (b) articles intended for use as a component of these  
 16 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  
 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,  
 4 part 21.

5 (9) "Device" (except when used in 50-31-107(2),  
 6 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
 7 50-31-501(10)) means instruments, apparatus, and  
 8 contrivances, including their components, parts, and  
 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 Pharmacopoeia, official Homeopathic Pharmacopoeia of the  
 17 United States, or official National Formulary or  
 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;

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

24 (d) articles intended for use as components of any  
 25 article specified in subsections (a), (b), or (c), but not

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;

8 (b) chewing gum; and

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

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

25 (b) This term does not include:

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;

6 (iii) color additive;

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,~~  
14 ~~catering vehicle, vending machine, delicatessen, fast-food~~  
15 ~~retailer, or any other place that serves food to the public~~  
16 ~~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.~~

19 ~~(15) "Hamburger" means comminuted GROUND fresh or~~  
20 ~~frozen beef or a combination of both fresh and frozen beef,~~  
21 ~~with or without the addition of suet, and with or without~~  
22 ~~the addition of seasoning, if no fat other than suet is~~  
23 ~~incorporated in the hamburger, the total fat content does~~  
24 ~~not exceed 20%, and no water, binders, or extenders are~~  
25 ~~added.~~

1        ~~{14}{116}~~ "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        ~~{17} "Imitation hamburger" means "hamburger", as~~  
7 ~~defined in subsection {14} {15}, to which has been added~~  
8 ~~binders or extenders or both binders and extenders as those~~  
9 ~~terms are understood by general custom and usage in the food~~  
10 ~~industry.~~

11        ~~{15}{118}~~ "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        ~~{16}{119}~~ "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        ~~{17}{121}~~ "New drug" means a drug the composition of  
22 which is such that:

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

1        for use under the conditions prescribed, recommended, or  
2 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        ~~{18}{122}~~ "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        ~~{19}{123}~~ "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;

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

25        ~~{20}{124}~~ "Person" includes an individual, partnership,

1 corporation, and association.

2       ~~(21)~~(25) "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.

9       ~~(26)~~ "Placard" means any nonpermanent sign used to  
10 display or describe food items for sale in a food service  
11 establishment.

12       ~~(22)~~(27) "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.

16       ~~(23)~~(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       ~~(24)~~(29) "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.

1       Section 2. Section 50-31-312, MCA, is amended to read:

2       "50-31-312. Exemptions from new drug application  
3 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).

18       (2) The provisions of 50-31-103~~(17)~~(21) shall not  
19 apply to any drug, when such drug is intended solely for use  
20 under conditions prescribed, recommended, or suggested in  
21 labeling with respect to such drug, which on October 9,  
22 1962, or on the date immediately preceding July 1, 1967:

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

25       (b) was not a new drug as defined by 50-31-103~~(17)~~(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."

4 Section 3. Section 50-31-506, MCA, is amended to read:

5 "50-31-506. Penalties. (1) Any person who violates any  
6 of the provisions of 50-31-204, 50-31-501, or 50-31-502, ~~or~~  
7 ~~[section 5 of this act]~~ shall be guilty of a misdemeanor and  
8 shall on conviction thereof be subject to imprisonment for  
9 not more than 3 months, a fine of not more than \$250, or  
10 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."

1 NEW SECTION. Section 5. Sale of hamburger and  
2 imitation hamburger. (1) No food service establishment may  
3 use the terms "hamburger", "burger", or other similar term  
4 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 ~~the~~ THE product as  
7 "imitation hamburger" or by any other term which accurately  
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 ~~(a) The ingredients must be listed in descending order~~  
15 ~~of predominance by weight.~~

16 ~~(b) (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 included, and~~

19 (B) THE INGREDIENTS MUST BE LISTED IN DESCENDING ORDER  
20 OF PREDOMINANCE BY WEIGHT.

21 ~~(c) If there is no menu, such THE lettering on the~~  
22 ~~wallboard or placard must be at least 1 inch in height~~  
23 ~~(72-point letters) in boldface AND in colors that contrast~~  
24 ~~with the wallboard or placard.~~

25 ~~(d) 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-

## 1 HOUSE BILL NO. 316

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

6  
7 A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE FOOD SERVICE  
8 ESTABLISHMENTS TO DISTINGUISH BETWEEN HAMBURGER AND  
9 IMITATION HAMBURGER IN ADVERTISEMENT OF PRODUCTS FOR SALE  
10 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  
14 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

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

16 "50-31-103. Definitions. Unless the context requires  
17 otherwise, in this chapter the following definitions apply:

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

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

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

1 (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

6 (ii) when added or applied to a food, drug, or cosmetic  
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;

17 (b) a commodity subject to packaging or labeling  
18 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;



1 (d) a beverage subject to or complying with packaging  
2 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:

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;

15 (b) articles intended for use as a component of these  
16 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  
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,  
4 part 21.

5 (9) "Device" (except when used in 50-31-107(2),  
6 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
7 50-31-501(10)) means instruments, apparatus, and  
8 contrivances, including their components, parts, and  
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 Pharmacopoeia, official Homeopathic Pharmacopoeia of the  
17 United States, or official National Formulary or a  
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;

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

24 (d) articles intended for use as components of any  
25 article specified in subsections (a), (b), or (c), but does

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;

8 (b) chewing gum; and

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

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

25 (b) This term does not include:

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;

6 (iii) color additive;

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,~~  
14 ~~catering vehicle, vending machine, delicatessen, fast-food~~  
15 ~~retailer, or any other place that serves food to the public~~  
16 ~~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.~~

19 (15) "Hamburger" means comminuted GROUND fresh or  
20 frozen beef or a combination of both fresh and frozen beef,  
21 with or without the addition of suet, and with or without  
22 the addition of seasoning, if no fat other than suet is  
23 incorporated in the hamburger, the total fat content does  
24 not exceed 20%, and no water, binders, or extenders are  
25 added.

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        ~~{17}~~ "Imitation hamburger" means "hamburger", as  
 7 defined in subsection ~~{14}~~ {15}, to which has been added  
 8 binders or extenders or both binders and extenders as those  
 9 terms are understood by general custom and usage in the food  
 10 industry.

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        ~~{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 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        ~~{17}~~{21} "New drug" means a drug the composition of  
 22 which is such that:

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

1 for use under the conditions prescribed, recommended, or  
 2 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        ~~{18}~~{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        ~~{19}~~{23} "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;

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

25        ~~{20}~~{24} "Person" includes an individual, partnership,

1 corporation, and association.

2 ~~(21)(25)~~ "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.

9 ~~(26)~~ "Placard" means any nonpermanent sign used to  
 10 display or describe food items for sale in a food service  
 11 establishment.

12 ~~(22)(27)~~ "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.

16 ~~(23)(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 ~~(24)(29)~~ "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."

1 Section 2. Section 50-31-312, MCA, is amended to read:  
 2 "50-31-312. Exemptions from new drug application  
 3 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).

18 (2) The provisions of 50-31-103~~(17)~~(21) shall not  
 19 apply to any drug, when such drug is intended solely for use  
 20 under conditions prescribed, recommended, or suggested in  
 21 labeling with respect to such drug, which on October 9,  
 22 1962, or on the date immediately preceding July 1, 1967:

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

25 (b) was not a new drug as defined by 50-31-103~~(17)~~(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."

4 Section 3. Section 50-31-506, MCA, is amended to read:

5 "50-31-506. Penalties. (1) Any person who violates any  
6 of the provisions of 50-31-204, 50-31-501, or 50-31-502, or  
7 [section 5 of this act] shall be guilty of a misdemeanor and  
8 shall on conviction thereof be subject to imprisonment for  
9 not more than 3 months, a fine of not more than \$250, or  
10 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."

1 NEW SECTION. Section 5. Sale of hamburger and  
2 imitation hamburger. (1) No food service establishment may  
3 use the terms "hamburger", "burger", or other similar term  
4 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 THE product as  
7 "imitation hamburger" or by any other term which accurately  
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 ~~(a) The ingredients must be listed in descending order~~  
15 ~~of predominance by weight.~~

16 ~~(b) (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 included, and~~

19 (B) THE INGREDIENTS MUST BE LISTED IN DESCENDING ORDER  
20 OF PREDOMINANCE BY WEIGHT.

21 ~~(c) If there is no menu, such THE lettering on the~~  
22 ~~wallboard or placard must be at least 1 inch in height~~  
23 ~~(72-point letters) in boldface AND in colors that contrast~~  
24 ~~with the wallboard or placard.~~

25 ~~(e) (D) The wallboard or placard must be posted in a~~

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-