HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES

IN THE HOUSE

FEBRUARY 14, 1989	INTRODUCED AND REFERRED TO COMMITTEE ON HUMAN SERVICES & AGING.
	FIRST READING.
FEBRUARY 18, 1989	COMMITTEE RECOMMEND BILL DO PASS AS AMENDED. REPORT ADOPTED.
FEBRUARY 20, 1989	PRINTING REPORT.
	SECOND READING, DO PASS.
FEBRUARY 21, 1989	ENGROSSING REPORT.
	THIRD READING, PASSED. AYES, 76; NOES, 23.
	TRANSMITTED TO SENATE.

IN THE SENATE

FEBRUARY 28, 1989	INTRODUCED AND REFERRED TO COMMITTEE ON PUBLIC HEALTH, WELFARE & SAFETY.
	FIRST READING.
MARCH 21, 1989	COMMITTEE RECOMMEND BILL BE CONCURRED IN AS AMENDED. REPORT ADOPTED.
MARCH 22, 1989	PASS CONSIDERATION.
MARCH 23, 1989	SECOND READING, CONCURRED IN AS AMENDED.
MARCH 28, 1989	THIRD READING, CONCURRED IN. AYES, 44; NOES, 6.

RETURNED TO HOUSE WITH AMENDMENTS.

IN THE HOUSE

MARCH 30, 1989

RECEIVED FROM SENATE.

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

HOUSE BILL NO. 688

INTRODUCED BY Simon Hager

BY REQUEST OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

Section 1. Section 37-2-104, MCA, is amended to read:

"**37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions.** (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of ~~such~~ a medical practitioner;

(c) dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;

(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;

(e) a medical practitioner from dispensing drug samples.;

(f) the dispensing of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if the dispensing is in accordance with:

(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) the drug labeling, storage, and logging requirements of the board of pharmacy."

Section 2. Section 37-7-103, MCA, is amended to read:

"**37-7-103. Exemptions.** Subject only to 37-7-401 and 37-7-402:

(1) nothing in this chapter subjects a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board or prevents such person from compounding or using drugs, medicines, chemicals, or poisons in his practice or prevents one duly licensed to practice medicine from furnishing to a patient such drugs, medicines, chemicals, or poisons as he considers proper in the treatment of ~~such~~ the patient;

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(2) nothing herein in this chapter prevents the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing herein in this chapter prevents the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes or in the arts or changes any of the provisions of this code relating to the sale of insecticides and fungicides, and nothing in this chapter prevents the sale of common household preparations and other drugs, provided stores selling them are licensed under the terms of this chapter;

(4) nothing herein in this chapter applies to or may interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes.;

(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing factory prepackaged oral contraceptives if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and with the board of pharmacy's requirements for labeling, storage, and logging of drugs."

Section 3. Section 50-31-307, MCA, is amended to read:

"50-31-307. Dispensing of prescription drugs. (1) A

drug intended for use by man which that falls in one of the categories in subsection (2) may be dispensed only:

~~(a) is a habit-forming drug to which 50-31-306(1)(d) applies;~~

~~(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or~~

~~(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer such drug shall be dispensed only:~~

~~(i)~~(a) upon a written prescription of a practitioner licensed by law to administer such the drug;

~~(ii)~~(b) upon an oral prescription of such the practitioner which that is reduced promptly to writing and filed by the pharmacist; or

~~(iii)~~(c) by refilling any such written or oral prescription if such the refilling is authorized by the prescriber either in the original prescription or by oral order which that is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection (1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer the drug.

(3) If the drug is a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and logging of drugs.

~~(2)~~(4) The act of dispensing a drug contrary to the provisions of this section ~~shall--be--deemed--to--be~~ is considered an act ~~which~~ that results in a drug being misbranded while held for sale."

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

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

(4) (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.

(5) "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, and toxin act;

(c) a drug subject to 50-31-306(1)(m) or ~~50-31-307(1)(c)~~ 50-31-307(2)(c) 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

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

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

(7) "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.

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

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

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

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

(b) to affect the structure or function of the body of

man or other animals.

(11) "Drug" means:

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

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

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

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

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

(13) "Food" means:

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

(b) chewing gum; and

(c) articles used for components of these articles.

(14) (a) "Food additive" means a substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food

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

(b) This term does not include:

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

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

(iii) a color additive;

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

(15) "Food service establishment" means a restaurant,

catering vehicle, vending machine, delicatessen, fast-food retailer, or any other place that serves food to the public for consumption either at or away from the point of service, and any facility operated by a governmental entity where food is served.

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

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

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

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

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

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

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

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

(b) accompanying the article.

(20) "Menu" means any list presented to the patron which states the food items for sale in a food service establishment.

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

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

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

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

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

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

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

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

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

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

(28) "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.

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

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

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

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

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

Section 5. Section 50-32-205, MCA, is amended to read:

"**50-32-205. Nonprescription drugs not to be scheduled.** The board shall exclude any nonnarcotic drug from a schedule if ~~such~~ the drug may, under the Federal Food, Drug, and

Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the Montana Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription."

NEW SECTION. **Section 6.** **Extension of authority.** Any existing authority to make rules on the subject of the provisions of [this act] is extended to the provisions of [this act].

NEW SECTION. **Section 7.** **Effective date.** [This act] is effective on passage and approval.

-End-

APPROVED BY COMM. ON
HUMAN SERVICES AND AGING

HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

Section 1. Section 37-2-104, MCA, is amended to read:

"**37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions.** (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of ~~such~~ a medical practitioner;

(c) dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;

(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;

(e) a medical practitioner from dispensing drug samples~~.~~;

(f) the dispensing of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if the dispensing is in accordance with:

(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) the drug labeling, storage, and ~~logging~~ RECORDKEEPING requirements of the board of pharmacy."

Section 2. Section 37-7-103, MCA, is amended to read:

"**37-7-103. Exemptions.** Subject only to 37-7-401 and 37-7-402:

(1) nothing in this chapter subjects a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board or prevents such person from compounding or using drugs, medicines, chemicals, or poisons in his practice or prevents one duly licensed to practice medicine from furnishing to a patient such drugs, medicines, chemicals, or poisons as he considers

proper in the treatment of ~~such~~ the patient;

(2) nothing ~~herein~~ in this chapter prevents the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing ~~herein~~ in this chapter prevents the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes or in the arts or changes any of the provisions of this code relating to the sale of insecticides and fungicides, and nothing in this chapter prevents the sale of common household preparations and other drugs, provided stores selling them are licensed under the terms of this chapter;

(4) nothing ~~herein~~ in this chapter applies to or may interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes~~.~~;

(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing factory prepackaged oral contraceptives if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and with the board of pharmacy's requirements for labeling, storage, and ~~logging~~ RECORDKEEPING of drugs."

Section 3. Section 50-31-307, MCA, is amended to read:

"**50-31-307. Dispensing of prescription drugs.** (1) A drug intended for use by man ~~which~~ that falls in one of the categories in subsection (2) may be dispensed only:

~~(a)--is--a--habit-forming-drug-to-which-50-31-306(1)(d) applies;~~

~~(b)--because-of-its-toxicity-or-other-potentiality--for harmful--effect,--the--method--of-its-use,-or-the-collateral measures-necessary-to-its-use,-is-not-safe--for--use--except under--the--supervision-of-a-practitioner-licensed-by-law-to administer-such-drug;-or~~

~~(c)--is--limited--by--an--approved--application---under section-505-of-the-federal-act-or-50-31-311-to-use-under-the professional--supervision--of-a-practitioner-licensed-by-law to-administer-such-drug-shall-be-dispensed-only:~~

~~(i)~~(a) upon a written prescription of a practitioner licensed by law to administer ~~such~~ the drug;

~~(ii)~~(b) upon an oral prescription of ~~such~~ the practitioner ~~which~~ that is reduced promptly to writing and filed by the pharmacist; or

~~(iii)~~(c) by refilling any ~~such~~ written or oral prescription if ~~such~~ the refilling is authorized by the prescriber either in the original prescription or by oral order ~~which~~ that is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection

(1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer the drug.

(3) If the drug is a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and ~~logging~~ RECORDKEEPING of drugs.

~~(2)~~(4) The act of dispensing a drug contrary to the provisions of this section ~~shall be deemed to be~~ is considered an act ~~which~~ that results in a drug being misbranded while held for sale."

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

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

(4) (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.

(5) "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, and toxin act;

(c) a drug subject to 50-31-306(1)(m) or ~~50-31-307(1)(c)~~ 50-31-307(2)(c) 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

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

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

(7) "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.

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

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

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

(a) for use in the diagnosis, cure, mitigation,

treatment, or prevention of disease in man or other animals;

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

(11) "Drug" means:

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

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

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

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

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

(13) "Food" means:

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

(b) chewing gum; and

(c) articles used for components of these articles.

(14) (a) "Food additive" means a substance, the intended use of which results or may be reasonably expected

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

(b) This term does not include:

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

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

(iii) a color additive;

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

1260), as amended and extended (21 U.S.C. 71, et seq.).

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

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

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

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

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

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

(18) "Label" means a display of written, printed, or

graphic matter on the immediate container of an article. ("Immediate container" does not include package liners.)

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

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

(b) accompanying the article.

(20) "Menu" means any list presented to the patron which states the food items for sale in a food service establishment.

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

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

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

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

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

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

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

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

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

(27) "Placard" means any nonpermanent sign used to display or describe food items for sale in a food service

establishment or retail establishment.

(28) "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.

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

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

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

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

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

Section 5. Section 50-32-205, MCA, is amended to read:

"**50-32-205. Nonprescription drugs not to be scheduled.** The board shall exclude any nonnarcotic drug from a schedule if such the drug may, under the Federal Food, Drug, and Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the Montana Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription."

NEW SECTION. **Section 6.** Extension of authority. Any existing authority to make rules on the subject of the provisions of [this act] is extended to the provisions of [this act].

NEW SECTION. **Section 7.** Effective date. [This act] is effective on passage and approval.

-End-

APPROVED BY COMM. ON
HUMAN SERVICES AND AGING

HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

Section 1. Section 37-2-104, MCA, is amended to read:

"**37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions.** (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of ~~such~~ a medical practitioner;

(c) dispensing a drug to a patient by a medical

There is no change on HB 688 and will not be reprinted. Please refer to second reading (yellow) for complete text.

THIRD READING

MR. PRESIDENT:

We, your committee on Public Health, Welfare, and Safety, having had under consideration HB 688 (third reading copy -- blue), respectfully report that HB 688 be amended and as so amended be concurred in:

Sponsor: Simon (Hager)

1. Page 2, lines 7 through 15.
Strike: subsection (f) in its entirety
Insert: "(f) the dispensing of the first month's cycle, or one month's emergency cycle in the event of an unscheduled appointment, of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if:

(i) the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) a registered pharmacist has prelabeled the factory packaged oral contraceptive for use as an initial or emergency cycle in accordance with Class IV regulations contained in Rule 8.40.706, Administrative Rules of Montana. The registered nurse shall complete the label by adding the patient's name and date of issue."

2. Page 3, lines 17 through 24.
Strike: subsection (5) in its entirety
Insert: "(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing the first month's cycle or an emergency cycle of a factory prepackaged oral contraceptive if:

(a) the dispensing is in accordance with the physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(b) a registered pharmacist has prelabeled the oral contraceptive in accordance with Class IV regulations contained in Rule 8.40.706, Administrative Rules of Montana."

3. Page 5, lines 13 through 21.
Strike: subsection (3) in its entirety
Insert: "(3) If the drug is the first month's cycle or an emergency cycle of a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the

continued

department of health and environmental sciences pursuant to:

(a) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(b) the board of pharmacy's rules for Class IV pharmacies contained in Rule 8.40.706, Administrative Rules of Montana."

AMD AS AMENDED BE CONCURRED IN

Signed: Tom Hager
Thomas O. Hager, Chairman

SENATE
HB 688

SENATE COMMITTEE OF THE WHOLE AMENDMENT

March 23, 1989 8:23 am

Mr. Chairman: I move to amend HB 688 (third reading copy -- blue) as follows:

1. Strike: The Senate Committee on Public Health, Welfare, and Safety amendments to HB 688 (third reading copy -- blue) dated March 20, 1989, in their entirety

ADOPT

REJECT

Signed: _____
Senator Hager

HB 688

SENATE

cwhb688.323

HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

Section 1. Section 37-2-104, MCA, is amended to read:

"37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions. (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of such a medical practitioner;

(c) dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;

(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;

(e) a medical practitioner from dispensing drug samples;

~~(f) the dispensing of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if the dispensing is in accordance with:~~

~~(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and~~

~~(ii) the drug labeling, storage, and logging~~ RECORDKEEPING requirements of the board of pharmacy:

~~(F) THE DISPENSING OF THE FIRST MONTH'S CYCLE, OR ONE MONTH'S EMERGENCY CYCLE IN THE EVENT OF AN UNSCHEDULED APPOINTMENT, OF FACTORY PREPACKAGED ORAL CONTRACEPTIVES BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES IF:~~

~~(I) THE DISPENSING IS IN ACCORDANCE WITH A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND~~

~~(II) A REGISTERED PHARMACIST HAS PRELABELED THE FACTORY~~

~~PACKAGED--ORAL--CONTRACEPTIVE--FOR--USE--AS--AN--INITIAL--OR EMERGENCY--CYCLE--IN--ACCORDANCE--WITH--CLASS-IV-REGULATIONS CONTAINED-IN-RULE-8.40.706,-ADMINISTRATIVE-RULES-OF-MONTANA. THE-REGISTERED-NURSE-SHALL-COMPLETE-THE-LABEL-BY-ADDING--THE PATIENT'S-NAME-AND-DATE-OF-ISSUE.~~

(F) THE DISPENSING OF FACTORY PREPACKAGED ORAL CONTRACEPTIVES BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES IF THE DISPENSING IS IN ACCORDANCE WITH:

(I) A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND

(II) THE DRUG LABELING, STORAGE, AND RECORDKEEPING REQUIREMENTS OF THE BOARD OF PHARMACY."

Section 2. Section 37-7-103, MCA, is amended to read:

"**37-7-103. Exemptions.** Subject only to 37-7-401 and 37-7-402:

(1) nothing in this chapter subjects a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board or prevents such person from compounding or using drugs, medicines, chemicals, or poisons in his practice or prevents one duly licensed to practice medicine from furnishing to a patient such drugs, medicines, chemicals, or poisons as he considers proper in the treatment of such the patient;

(2) nothing herein in this chapter prevents the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing herein in this chapter prevents the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes or in the arts or changes any of the provisions of this code relating to the sale of insecticides and fungicides, and nothing in this chapter prevents the sale of common household preparations and other drugs, provided stores selling them are licensed under the terms of this chapter;

(4) nothing herein in this chapter applies to or may interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes~~.~~;

~~(5)--nothing-in--this--chapter--prevents--a--registered nurse--employed--by--a-family-planning-clinic-under-contract with-the-department-of--health--and--environmental--sciences from--dispensing--factory-prepackaged-oral-contraceptives-if the-dispensing-is-in-accordance-with-a--physician's--written protocol-specifying-the-circumstances-under-which-dispensing is-appropriate-and-with-the-board-of-pharmacy's-requirements for--labeling,--storage,-and logging~~ RECORDKEEPING ~~of-drugs.~~

~~(5)--NOTHING-IN--THIS--CHAPTER--PREVENTS--A--REGISTERED NURSE--EMPLOYED--BY--A-FAMILY-PLANNING-CLINIC-UNDER-CONTRACT~~

WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES FROM DISPENSING THE FIRST MONTH'S CYCLE OR AN EMERGENCY CYCLE OF A FACTORY PREPACKAGED ORAL CONTRACEPTIVE IF:

(A) THE DISPENSING IS IN ACCORDANCE WITH THE PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND

(B) A REGISTERED PHARMACIST HAS PRELABELED THE ORAL CONTRACEPTIVE IN ACCORDANCE WITH CLASS IV REGULATIONS CONTAINED IN RULE 8.40.706, ADMINISTRATIVE RULES OF MONTANA.

(5) NOTHING IN THIS CHAPTER PREVENTS A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES FROM DISPENSING FACTORY PREPACKAGED ORAL CONTRACEPTIVES IF THE DISPENSING IS IN ACCORDANCE WITH A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE AND WITH THE BOARD OF PHARMACY'S REQUIREMENTS FOR LABELING, STORAGE, AND RECORDKEEPING OF DRUGS."

Section 3. Section 50-31-307, MCA, is amended to read:

"50-31-307. Dispensing of prescription drugs. (1) A drug intended for use by man which that falls in one of the categories in subsection (2) may be dispensed only:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral

measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer such drug shall be dispensed only:

(i)(a) upon a written prescription of a practitioner licensed by law to administer such the drug;

(ii)(b) upon an oral prescription of such the practitioner which that is reduced promptly to writing and filed by the pharmacist; or

(iii)(c) by refilling any such written or oral prescription if such the refilling is authorized by the prescriber either in the original prescription or by oral order which that is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection (1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to

administer the drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer the drug.

~~(3) If the drug is a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and logging~~ RECORDKEEPING of drugs:

~~(3) IF THE DRUG IS THE FIRST MONTH'S CYCLE OR AN EMERGENCY CYCLE OF A FACTORY PREPACKAGED ORAL CONTRACEPTIVE, IT MAY BE DISPENSED AS PROVIDED IN SUBSECTION (1) OR BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES PURSUANT TO:~~

~~(A) A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND~~

~~(B) THE BOARD OF PHARMACY'S RULES FOR CLASS IV PHARMACIES CONTAINED IN RULE 8.40.706, ADMINISTRATIVE RULES OF MONTANA;~~

(3) IF THE DRUG IS A FACTORY PREPACKAGED ORAL CONTRACEPTIVE, IT MAY BE DISPENSED AS PROVIDED IN SUBSECTION (1) OR BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES PURSUANT TO A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE AND PURSUANT TO THE BOARD OF PHARMACY'S RULES CONCERNING LABELING, STORAGE, AND RECORDKEEPING OF DRUGS.

~~(2)~~(4) The act of dispensing a drug contrary to the provisions of this section ~~shall be deemed to be~~ is considered an act ~~which~~ that results in a drug being misbranded while held for sale."

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

(3) "Color" includes black, white, and intermediate

grays.

(4) (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.

(5) "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, and toxin act;

(c) a drug subject to 50-31-306(1)(m) or ~~50-31-307(1)(c)~~ 50-31-307(2)(c) 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

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

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

(7) "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.

(8) "Counterfeit drug" means a drug, drug container, or drug label which, without authorization bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof of a drug manufacturer, processor, packer, or distributor other than the person who in fact manufactured, processed, packed, or distributed the

drug and which falsely purports or is represented to be the product of or to have been packed or distributed by the other drug manufacturer, processor, packer, or distributor.

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

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

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

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

(11) "Drug" means:

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

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

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

(d) articles intended for use as components of any

article specified in subsections (a), (b), or (c) but does not include devices or their components, parts, or accessories.

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

(13) "Food" means:

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

(b) chewing gum; and

(c) articles used for components of these articles.

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

(b) This term does not include:

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

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

(iii) a color additive;

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

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

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

(a) "economy hamburger" or "economy ground beef" may

have a fat content no greater than the federal standard set forth in 9 C.F.R. 319.15;

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

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

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

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

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

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

(b) accompanying the article.

(20) "Menu" means any list presented to the patron which states the food items for sale in a food service establishment.

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

(a) it is not generally recognized, among experts qualified by scientific training and experience to evaluate

the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling; or

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

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

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

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

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

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

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

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

(28) "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.

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

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

marketing.

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

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

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

Section 5. Section 50-32-205, MCA, is amended to read:

"**50-32-205. Nonprescription drugs not to be scheduled.** The board shall exclude any nonnarcotic drug from a schedule if ~~such~~ the drug may, under the Federal Food, Drug, and Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the Montana Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription."

NEW SECTION. **Section 6. Extension of authority.** Any existing authority to make rules on the subject of the provisions of [this act] is extended to the provisions of [this act].

NEW SECTION. **Section 7. Effective date.** [This act] is effective on passage and approval.

-End-