

CHAPTER NO. 403

SENATE BILL NO. 377

INTRODUCED BY PALMER, REGAN, BOYLAN

IN THE SENATE

February 6, 1979	Introduced and referred to Committee on Public Health, Welfare, and Safety.
February 14, 1979	Committee recommend bill do pass as amended. Report adopted.
February 16, 1979	Printed and placed on members' desks.
February 17, 1979	Second reading, do pass as amended.
February 19, 1979	Correctly engrossed.
February 20, 1979	Third reading, passed. Transmitted to second house.

IN THE HOUSE

February 21, 1979	Introduced and referred to Committee on Human Services.
March 8, 1979	Committee recommend bill be concurred in. Report adopted.
March 12, 1979	Consideration passed until 59th Legislative Day.
March 14, 1979	Second reading, concurred in as amended.
March 16, 1979	Third reading, concurred in as amended.

IN THE SENATE

March 17, 1979	Returned from second house. Concurred in as amended.
----------------	--

March 19, 1979

Second reading, pass consideration.

March 20, 1979

Second reading, amendments
adopted.

March 21, 1979

Third reading, amendments
adopted. Sent to enrolling.

Reported correctly enrolled.

1 *Senate* BILL NO. *377*
 2 INTRODUCED BY *Fabian Riquelme*
 3

4 A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE THE
 5 IDENTIFICATION OF THE ACTUAL MANUFACTURER OF ALL DRUG
 6 PRODUCTS IN ORDER TO FACILITATE THE IMPLEMENTATION OF THE
 7 MONTANA DRUG PRODUCT SELECTION ACT; AMENDING SECTIONS
 8 50-31-301 AND 50-31-306, MCA."
 9

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

11 Section 1. Section 50-31-301, MCA, is amended to read:
 12 "50-31-301. Definitions. ~~(1)~~ As used in this part, the
 13 term following definitions apply:

14 (1) "established ~~Established~~ name", with respect to a
 15 drug or ingredient thereof, means:

16 (a) the applicable official name designated pursuant
 17 to section 508 of the federal act;

18 (b) if there is no such name and such drug or such
 19 ingredient is an article recognized in an official
 20 compendium, then the official title thereof in such
 21 compendium; or provided that, where subsection (1)(b) of
 22 this section applies to an article recognized in the United
 23 States Pharmacopoeia and in the Homeopathic Pharmacopoeia
 24 under different official titles, the official title used in
 25 the United States Pharmacopoeia shall apply unless it is

1 labeled and offered for sale as a homeopathic drug, in which
 2 case the official title used in the Homeopathic
 3 Pharmacopoeia shall apply;

4 (c) if neither subsection (1)(a) nor (1)(b) of this
 5 section applies, then the common or usual name, if any, of
 6 such drug or of such ingredient.

7 ~~(2) For the purpose of this part, the term "antibiotic~~
 8 ~~Antibiotic~~ drug" means any drug intended for use by man
 9 containing any quantity of any chemical substance which is
 10 produced by a microorganism and which has the capacity to
 11 inhibit or destroy microorganisms in dilute solution
 12 (including the chemically synthesized equivalent of any such
 13 substance).

14 ~~(3) "Manufacturer" means a person who fixed the final~~
 15 ~~ingredients and prepared the final drug product."~~

16 Section 2. Section 50-31-306, MCA, is amended to read:
 17 "50-31-306. When drug or device misbranded. (1) A drug
 18 or device shall be deemed to be misbranded:

19 (a) if its labeling is false or misleading in any
 20 particular;

21 (b) if in package form unless it bears a label
 22 containing:

23 (i) the name and place of business of the
 24 manufacturer, as well as the packery or distributor; and

25 (ii) an accurate statement of the quantity of the

1 contents in terms of weight, measure, or numerical count;
 2 provided that reasonable variation shall be permitted and
 3 exemptions as to small packages shall be allowed in
 4 accordance with regulations prescribed by the department or
 5 issued under the federal act;

6 (c) if any word, statement, or other information
 7 required by or under authority of this chapter to appear on
 8 the label or labeling is not prominently placed thereon with
 9 such conspicuousness (as compared with other words,
 10 statements, designs, or devices in the labeling) and in such
 11 terms as to render it likely to be read and understood by
 12 the ordinary individual under customary conditions of
 13 purchase and use;

14 (d) if it is for use by man and contains any quantity
 15 of the narcotic or hypnotic substance alpha-eucaine,
 16 barbituric acid, beta-eucaine, bromal, cannabis, carbomal,
 17 chloral, coca, cocaine, codeine, heroin, marihuana,
 18 morphine, opium, paraldehyde, peyote, sulphonmethane, or any
 19 chemical derivative of such substance which, after
 20 investigation, has been found to be and designated as
 21 habit-forming by regulations issued by the department under
 22 this chapter or by regulations issued pursuant to section
 23 502(d) of the federal act, unless its label bears the name
 24 and quantity or proportion of such substance or derivative
 25 and in juxtaposition therewith the statement "Warning--May

1 be habit-forming";

2 (e) if it is a drug, unless its label bears to the
 3 exclusion of any other nonproprietary name (except the
 4 applicable systematic chemical name or the chemical
 5 formula):

6 (i) the established name (as defined in 50-31-301(1))
 7 of the drug, if such there be; and

8 (ii) in case it is fabricated from two or more
 9 ingredients, the established name and quantity of each
 10 active ingredient, including the kind and quantity or
 11 proportion of any alcohol and also including, whether active
 12 or not, the established name and quantity or proportion of
 13 any bromides, ether, chloroform, acetanilid, acetphenetidin,
 14 amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine,
 15 arsenic, digitalis, digitalis glucosides, mercury, ouabain,
 16 strophanthin, strychnine, thyroid, or any derivative or
 17 preparation of any such substances contained therein
 18 provided that the requirement for stating the quantity of
 19 the active ingredients, other than the quantity of those
 20 specifically named in this subsection (1)(e)(ii), shall
 21 apply only to prescription drugs; provided further that, to
 22 the extent that compliance with the requirements of this
 23 subsection (1)(e)(ii) is impracticable, exemptions shall be
 24 allowed under regulations promulgated by the department or
 25 under the federal act;

1 (f) unless its labeling bears:

2 (i) adequate directions for use; provided that, where
3 any requirement of this subsection (1)(f)(i), as applied to
4 any drug or device, is not necessary for the protection of
5 the public health, the department shall promulgate
6 regulations exempting such drug or device from such
7 requirements; provided further that articles exempted under
8 regulations issued under section 502(f) of the federal act
9 may also be exempt; and

10 (ii) such adequate warnings against use in those
11 pathological conditions or by children where its use may be
12 dangerous to health, or against unsafe dosage or methods or
13 duration of administration or application, in such manner
14 and form as are necessary for the protection of users;

15 (g) if it purports to be a drug the name of which is
16 recognized in an official compendium, unless it is packaged
17 and labeled as prescribed therein; provided that the method
18 of packing may be modified with the consent of the
19 department or if consent is obtained under the federal act.
20 Whenever a drug is recognized in both the United States
21 Pharmacopoeia and the Homeopathic Pharmacopoeia of the
22 United States, it shall be subject to the requirement of the
23 United States Pharmacopoeia with respect to packaging and
24 labeling unless it is labeled and offered for sale as a
25 homeopathic drug, in which case it shall be subject to the

1 provisions of the Homeopathic Pharmacopoeia of the United
2 States and not to those of the United States Pharmacopoeia;
3 provided further that, in the event of inconsistency between
4 the requirements of this subsection and those of subsection
5 (e) as to the name by which the drug or its ingredients
6 shall be designated, the requirements of subsection (e)
7 shall prevail.

8 (h) if it has been found by the department or under
9 the federal act to be a drug liable to deterioration, unless
10 it is packaged in such form and manner and its label bears a
11 statement of such precautions as the regulations issued by
12 the department or under the federal act require as necessary
13 for the protection of public health. No such regulation
14 shall be established for any drug recognized in an official
15 compendium until the department shall have informed the
16 appropriate body charged with the revision of such
17 compendium of the need for such packaging or labeling
18 requirements and such body shall have failed within a
19 reasonable time to prescribe such requirements.

20 (i) if it is a drug and its container is so made,
21 formed, or filled as to be misleading;

22 (j) if it is an imitation of another drug;

23 (k) if it is offered for sale under the name of
24 another drug;

25 (l) if it is dangerous to health when used in the

1 dosage or with the frequency or duration prescribed,
2 recommended, or suggested in the labeling thereof;

3 (m) if it is, purports to be, or is represented as a
4 drug composed wholly or partly of insulin, unless:

5 (i) it is from a batch with respect to which a
6 certificate or release has been issued pursuant to section
7 506 of the federal act; and

8 (ii) such certificate or release is in effect with
9 respect to such drug;

10 (n) if it is, purports to be, or is represented as a
11 drug composed wholly or partly of any kind of penicillin,
12 streptomycin, chlortetracycline, chloramphenicol,
13 bacitracin, any other antibiotic drug, or any derivative
14 thereof, unless:

15 (i) it is from a batch with respect to which a
16 certificate or release has been issued pursuant to section
17 507 of the federal act; and

18 (ii) such certificate or release is in effect with
19 respect to such drug; provided that subsection (1)(n) shall
20 not apply to any drug or class of drugs exempted by
21 regulations promulgated under section 507(c) or (d) of the
22 federal act;

23 (o) if it is a color additive, the intended use of
24 which in or on drugs is for the purpose of coloring only,
25 unless its packaging and labeling are in conformity with

1 such packaging and labeling requirements applicable to such
2 color additive prescribed under the provisions of 50-31-108
3 or of the federal act;

4 (p) in the case of any prescription drug distributed
5 or offered for sale in this state, unless the manufacturer,
6 packer, or distributor thereof includes in all
7 advertisements and other descriptive printed matter issued
8 or caused to be issued by the manufacturer, packer, or
9 distributor with respect to that drug a true statement of:

10 (i) the established name, as defined in 50-31-301(1);

11 (ii) the formula showing quantitatively each ingredient
12 of such drug to the extent required for labels under section
13 502(e) of the federal act; and

14 (iii) such other information in brief summary relating
15 to side effects, contraindications, and effectiveness as
16 shall be required in regulations issued under the federal
17 act;

18 (q) if a trademark, trade name, or other identifying
19 mark, imprint, or device or another or any likeness of the
20 foregoing has been placed thereon or upon its container with
21 intent to defraud.

22 (2) A drug which is subject to 50-31-307 shall be
23 deemed to be misbranded if, at any time prior to dispensing,
24 its label fails to bear the statement "Caution: Federal Law
25 Prohibits Dispensing Without Prescription", or "Caution:

LC 1352/01

1 State Law Prohibits Dispensing Without Prescription*. A
2 drug to which 50-31-307 does not apply shall be deemed to be
3 misbranded if, at any time prior to dispensing, its label
4 bears the caution statement quoted in the preceding
5 sentence.*

-End-

1 (ii) an accurate statement of the quantity of the
2 contents in terms of weight, measure, or numerical count;
3 provided that reasonable variation shall be permitted and
4 exemptions as to small packages shall be allowed in
5 accordance with regulations prescribed by the department or
6 issued under the federal act;

7 (c) if any words, statement, or other information
8 required by or under authority of this chapter to appear on
9 the label or labeling is not prominently placed thereon with
10 such conspicuousness (as compared with other words,
11 statements, designs, or devices in the labeling) and in such
12 terms as to render it likely to be read and understood by
13 the ordinary individual under customary conditions of
14 purchase and use;

15 (d) if it is for use by man and contains any quantity
16 of the narcotic or hypnotic substance alpha-eucaine,
17 barbituric acid, beta-eucaine, bromal, cannabis, carbromal,
18 chloral, coca, cocaine, codeine, heroin, marihuana,
19 morphine, opium, paraldehyde, peyote, sulphonmethane, or any
20 chemical derivative of such substance which, after
21 investigation, has been found to be and designated as
22 habit-forming by regulations issued by the department under
23 this chapter or by regulations issued pursuant to section
24 502(d) of the federal act, unless its label bears the name
25 and quantity or proportion of such substance or derivative

1 and in juxtaposition therewith the statement "Warning--May
2 be habit-forming";

3 (e) if it is a drug, unless its label bears to the
4 exclusion of any other nonproprietary name (except the
5 applicable systematic chemical name or the chemical
6 formula):

7 (i) the established name (as defined in 50-31-301(1))
8 of the drug, if such there be; and

9 (ii) in case it is fabricated from two or more
10 ingredients, the established name and quantity of each
11 active ingredient, including the kind and quantity or
12 proportion of any alcohol and also including, whether active
13 or not, the established name and quantity or proportion of
14 any bromides, ether, chloroform, acetanilid, acetphenetidin,
15 amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine,
16 arsenic, digitalis, digitalis glucosides, mercury, ouabain,
17 strophanthin, strychnine, thyroid, or any derivative or
18 preparation of any such substances contained there,
19 provided that the requirement for stating the quantity of
20 the active ingredients, other than the quantity of those
21 specifically named in this subsection (1)(e)(ii), shall
22 apply only to prescription drugs; provided further that, to
23 the extent that compliance with the requirements of this
24 subsection (1)(e)(ii) is impracticable, exemptions shall be
25 allowed under regulations promulgated by the department or

1 under the federal act;

2 (f) unless its labeling bears:

3 (i) adequate directions for use; provided that, where
4 any requirement of this subsection (1)(f)(i), as applied to
5 any drug or device, is not necessary for the protection of
6 the public health, the department shall promulgate
7 regulations exempting such drug or device from such
8 requirements; provided further that articles exempted under
9 regulations issued under section 502(f) of the federal act
10 may also be exempt; and

11 (ii) such adequate warnings against use in those
12 pathological conditions or by children where its use may be
13 dangerous to health, or against unsafe dosage or methods or
14 duration of administration or application, in such manner
15 and form as are necessary for the protection of users;

16 (g) if it purports to be a drug the name of which is
17 recognized in an official compendium, unless it is packaged
18 and labeled as prescribed therein; provided that the method
19 of packing may be modified with the consent of the
20 department or if consent is obtained under the federal act.
21 Whenever a drug is recognized in both the United States
22 Pharmacopoeia and the Homeopathic Pharmacopoeia of the
23 United States, it shall be subject to the requirement of the
24 United States Pharmacopoeia with respect to packaging and
25 labeling unless it is labeled and offered for sale as a

1 homeopathic drug, in which case it shall be subject to the
2 provisions of the Homeopathic Pharmacopoeia of the United
3 States and not to those of the United States Pharmacopoeia;
4 provided further that, in the event of inconsistency between
5 the requirements of this subsection and those of subsection
6 (e) as to the name by which the drug or its ingredients
7 shall be designated, the requirements of subsection (e)
8 shall prevail.

9 (h) if it has been found by the department or under
10 the federal act to be a drug liable to deterioration, unless
11 it is packaged in such form and manner and its label bears a
12 statement of such precautions as the regulations issued by
13 the department or under the federal act require as necessary
14 for the protection of public health. No such regulation
15 shall be established for any drug recognized in an official
16 compendium until the department shall have informed the
17 appropriate body charged with the revision of such
18 compendium of the need for such packaging or labeling
19 requirements and such body shall have failed within a
20 reasonable time to prescribe such requirements.

21 (i) if it is a drug and its container is so made,
22 formed, or filled as to be misleading;

23 (j) if it is an imitation of another drug;

24 (k) if it is offered for sale under the name of
25 another drug;

1 (l) if it is dangerous to health when used in the
2 dosage or with the frequency or duration prescribed,
3 recommended, or suggested in the labeling thereof;

4 (m) if it is, purports to be, or is represented as a
5 drug composed wholly or partly of insulin, unless:

6 (i) it is from a batch with respect to which a
7 certificate or release has been issued pursuant to section
8 506 of the federal act; and

9 (ii) such certificate or release is in effect with
10 respect to such drug;

11 (n) if it is, purports to be, or is represented as a
12 drug composed wholly or partly of any kind of penicillin,
13 streptomycin, chlortetracycline, chloramphenicol,
14 bacitracin, any other antibiotic drug, or any derivative
15 thereof, unless:

16 (i) it is from a batch with respect to which a
17 certificate or release has been issued pursuant to section
18 507 of the federal act; and

19 (ii) such certificate or release is in effect with
20 respect to such drug; provided that subsection (l)(n) shall
21 not apply to any drug or class of drugs exempted by
22 regulations promulgated under section 507(c) or (d) of the
23 federal act;

24 (o) if it is a color additive, the intended use of
25 which in or on drugs is for the purpose of coloring only,

1 unless its packaging and labeling are in conformity with
2 such packaging and labeling requirements applicable to such
3 color additive prescribed under the provisions of 50-31-108
4 or of the federal act;

5 (p) in the case of any prescription drug distributed
6 or offered for sale in this state, unless the manufacturer,
7 packer, or distributor thereof includes in all
8 advertisements and other descriptive printed matter issued
9 or caused to be issued by the manufacturer, packer, or
10 distributor with respect to that drug a true statement of:

11 (i) the established name, as defined in 50-31-301(1);

12 (ii) the formula showing quantitatively each ingredient
13 of such drug to the extent required for labels under section
14 502(e) of the federal act; and

15 (iii) such other information in brief summary relating
16 to side effects, contraindications, and effectiveness as
17 shall be required in regulations issued under the federal
18 act;

19 (q) if a trademark, trade name, or other identifying
20 mark, imprint, or device or another or any likeness of the
21 foregoing has been placed thereon or upon its container with
22 intent to defraud.

23 (2) A drug which is subject to 50-31-307 shall be
24 deemed to be misbranded if, at any time prior to dispensing,
25 its label fails to bear the statement "Caution: Federal Law

1 Prohibits Dispensing Without Prescription", or "Caution:
2 State Law Prohibits Dispensing Without Prescription". A
3 drug to which 50-31-307 does not apply shall be deemed to be
4 misbranded if, at any time prior to dispensing, its label
5 bears the caution statement quoted in the preceding
6 sentence."

7 SECTION 3. EFFECTIVE DATE. THIS ACT IS EFFECTIVE
8 JANUARY 1, 1980.

-End-

SENATE BILL NO. 377

INTRODUCED BY PALMER, REGAN, BOYLAN

A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE THE IDENTIFICATION OF THE ACTUAL MANUFACTURER OF ALL DRUG PRODUCTS IN ORDER TO FACILITATE THE IMPLEMENTATION OF THE MONTANA DRUG PRODUCT SELECTION ACT; AMENDING SECTIONS 50-31-301 AND 50-31-306, MCA; ~~AND PROVIDING AN EFFECTIVE DATE.~~"

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

Section 1. Section 50-31-301, MCA, is amended to read:

"50-31-301. Definitions. ~~{}~~ As used in this part, the term following definitions apply:

(1) "established ~~Established~~ name", with respect to a drug or ingredient thereof, means:

(a) the applicable official name designated pursuant to section 508 of the federal act;

(b) if there is no such name and such drug or such ingredient is an article recognized in an official compendium, then the official title thereof in such compendium; or provided that, where subsection (1)(b) of this section applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in

the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply;

(c) if neither subsection (1)(a) nor (1)(b) of this section applies, then the common or usual name, if any, of such drug or of such ingredient.

~~(2) For the purpose of this part, the term "antibiotic drug"~~ means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

~~(3) "Manufacturer" means a person who fixed MIXED the final ingredients and prepared the final drug products."~~

Section 2. Section 50-31-306, MCA, is amended to read:

"50-31-306. When drug or device misbranded. (1) A drug or device shall be deemed to be misbranded:

(a) if its labeling is false or misleading in any particular;

(b) if in package form unless it bears a label containing:

(i) the name and place of business of the manufacturer, ~~as well as the packer~~ or distributor ~~IF~~

DIFFERENT THAN THAT OF THE MANUFACTURER; and

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided that reasonable variation shall be permitted and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the department or issued under the federal act;

(c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) if it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphomethane, or any chemical derivative of such substance which, after investigation, has been found to be and designated as habit-forming by regulations issued by the department under this chapter or by regulations issued pursuant to section 502(d) of the federal act, unless its label bears the name

and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit-forming";

(e) if it is a drug, unless its label bears to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula):

(i) the established name (as defined in 50-31-301(1)) of the drug, if such there be; and

(ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein; provided that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subsection (1)(e)(ii), shall apply only to prescription drugs; provided further that, to the extent that compliance with the requirements of this subsection (1)(e)(ii) is impracticable, exemptions shall be

1 allowed under regulations promulgated by the department or
2 under the federal act;

3 (f) unless its labeling bears:

4 (i) adequate directions for use; provided that, where
5 any requirement of this subsection (1)(f)(i), as applied to
6 any drug or device, is not necessary for the protection of
7 the public health, the department shall promulgate
8 regulations exempting such drug or device from such
9 requirements; provided further that articles exempted under
10 regulations issued under section 502(f) of the federal act
11 may also be exempt; and

12 (ii) such adequate warnings against use in those
13 pathological conditions or by children where its use may be
14 dangerous to health, or against unsafe dosage or methods or
15 duration of administration or application, in such manner
16 and form as are necessary for the protection of users;

17 (g) if it purports to be a drug the name of which is
18 recognized in an official compendium, unless it is packaged
19 and labeled as prescribed therein; provided that the method
20 of packing may be modified with the consent of the
21 department or if consent is obtained under the federal act.
22 Whenever a drug is recognized in both the United States
23 Pharmacopoeia and the Homeopathic Pharmacopoeia of the
24 United States, it shall be subject to the requirement of the
25 United States Pharmacopoeia with respect to packaging and

1 labeling unless it is labeled and offered for sale as a
2 homeopathic drug, in which case it shall be subject to the
3 provisions of the Homeopathic Pharmacopoeia of the United
4 States and not to those of the United States Pharmacopoeia;
5 provided further that, in the event of inconsistency between
6 the requirements of this subsection and those of subsection
7 (e) as to the name by which the drug or its ingredients
8 shall be designated, the requirements of subsection (e)
9 shall prevail.

10 (h) if it has been found by the department or under
11 the federal act to be a drug liable to deterioration, unless
12 it is packaged in such form and manner and its label bears a
13 statement of such precautions as the regulations issued by
14 the department or under the federal act require as necessary
15 for the protection of public health. No such regulation
16 shall be established for any drug recognized in an official
17 compendium until the department shall have informed the
18 appropriate body charged with the revision of such
19 compendium of the need for such packaging or labeling
20 requirements and such body shall have failed within a
21 reasonable time to prescribe such requirements.

22 (i) if it is a drug and its container is so made,
23 formed, or filled as to be misleading;

24 (j) if it is an imitation of another drug;

25 (k) if it is offered for sale under the name of

1 another drug;

2 (l) if it is dangerous to health when used in the
3 dosage or with the frequency or duration prescribed,
4 recommended, or suggested in the labeling thereof;

5 (m) if it is, purports to be, or is represented as a
6 drug composed wholly or partly of insulin, unless:

7 (i) it is from a batch with respect to which a
8 certificate or release has been issued pursuant to section
9 506 of the federal act; and

10 (ii) such certificate or release is in effect with
11 respect to such drug;

12 (n) if it is, purports to be, or is represented as a
13 drug composed wholly or partly of any kind of penicillin,
14 streptomycin, chlortetracycline, chloramphenicol,
15 bacitracin, any other antibiotic drug, or any derivative
16 thereof, unless:

17 (i) it is from a batch with respect to which a
18 certificate or release has been issued pursuant to section
19 507 of the federal act; and

20 (ii) such certificate or release is in effect with
21 respect to such drug; provided that subsection (l)(n) shall
22 not apply to any drug or class of drugs exempted by
23 regulations promulgated under section 507(c) or (d) of the
24 federal act;

25 (o) if it is a color additive, the intended use of

1 which in or on drugs is for the purpose of coloring only,
2 unless its packaging and labeling are in conformity with
3 such packaging and labeling requirements applicable to such
4 color additive prescribed under the provisions of 50-31-108
5 or of the federal act;

6 (p) in the case of any prescription drug distributed
7 or offered for sale in this state, unless the manufacturer,
8 packer, or distributor thereof includes in all
9 advertisements and other descriptive printed matter issued
10 or caused to be issued by the manufacturer, packer, or
11 distributor with respect to that drug a true statement of:

12 (i) the established name, as defined in 50-31-301(1);
13 (ii) the formula showing quantitatively each ingredient
14 of such drug to the extent required for labels under section
15 502(e) of the federal act; and

16 (iii) such other information in brief summary relating
17 to side effects, contraindications, and effectiveness as
18 shall be required in regulations issued under the federal
19 act;

20 (q) if a trademark, trade name, or other identifying
21 mark, imprint, or device or another or any likeness of the
22 foregoing has been placed thereon or upon its container with
23 intent to defraud.

24 (2) A drug which is subject to 50-31-307 shall be
25 deemed to be misbranded if, at any time prior to dispensing,

1 its label fails to bear the statement "Caution: Federal Law
2 Prohibits Dispensing Without Prescription", or "Caution:
3 State Law Prohibits Dispensing Without Prescription". A
4 drug to which 50-31-307 does not apply shall be deemed to be
5 misbranded if, at any time prior to dispensing, its label
6 bears the caution statement quoted in the preceding
7 sentence."

8 SECTION 3. EFFECTIVE DATE. THIS ACT IS EFFECTIVE
9 JANUARY 1, 1980.

-End-

SENATE BILL NO. 377

INTRODUCED BY PALMER, REGAN, BOYLAN

A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE THE IDENTIFICATION OF THE ACTUAL MANUFACTURER OF ALL DRUG PRODUCTS IN ORDER TO FACILITATE THE IMPLEMENTATION OF THE MONTANA DRUG PRODUCT SELECTION ACT; AMENDING SECTIONS 50-31-301 AND 50-31-306, MCA; ~~AND PROVIDING AN EFFECTIVE DATE.~~"

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

Section 1. Section 50-31-301, MCA, is amended to read:

"50-31-301. Definitions. ~~{}~~ As used in this part, the term following definitions apply:

(1) "established ~~Established~~ name", with respect to a drug or ingredient thereof, means:

(a) the applicable official name designated pursuant to section 508 of the federal act;

(b) if there is no such name and such drug or such ingredient is an article recognized in an official compendium, then the official title thereof in such compendium; or provided that, where subsection (1)(b) of this section applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in

the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply;

(c) if neither subsection (1)(a) nor (1)(b) of this section applies, then the common or usual name, if any, of such drug or of such ingredient.

~~(2) For the purpose of this part, the term "antibiotic~~ Antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

~~(3) "Manufacturer" means a person who fixed~~ MIXED the final ingredients and prepared the final drug product."

Section 2. Section 50-31-306, MCA, is amended to read:

"50-31-306. When drug or device misbranded. (1) A drug or device shall be deemed to be misbranded:

(a) if its labeling is false or misleading in any particular;

(b) if in package form unless it bears a label containing:

(i) the name and place of business of the manufacturer, ~~as well as~~ the packer, or distributor ~~if~~

1 DIFFERENTI--THAN--THAT--OF--THE--MANUFACTURER, EXCEPT THAT A
 2 PRESCRIPTION DRUG MUST CONTAIN THE NAME AND PLACE OF
 3 BUSINESS OF THE MANUFACTURER AS WELL AS THE PACKER OR
 4 DISTRIBUTOR; and

5 (ii) an accurate statement of the quantity of the
 6 contents in terms of weight, measure, or numerical count;
 7 provided that reasonable variation shall be permitted and
 8 exemptions as to small packages shall be allowed in
 9 accordance with regulations prescribed by the department or
 10 issued under the federal act;

11 (c) if any word, statement, or other information
 12 required by or under authority of this chapter to appear on
 13 the label or labeling is not prominently placed thereon with
 14 such conspicuousness (as compared with other words,
 15 statements, designs, or devices in the labeling) and in such
 16 terms as to render it likely to be read and understood by
 17 the ordinary individual under customary conditions of
 18 purchase and use;

19 (d) if it is for use by man and contains any quantity
 20 of the narcotic or hypnotic substance alpha-eucaine,
 21 barbituric acid, beta-eucaine, bromal, cannabis, carbromal,
 22 chloral, coca, cocaine, codeine, heroin, marijuana,
 23 morphine, opium, paraldehyde, peyote, sulphonmethane, or any
 24 chemical derivative of such substance which, after
 25 investigation, has been found to be and designated as

1 habit-forming by regulations issued by the department under
 2 this chapter or by regulations issued pursuant to section
 3 502(d) of the federal act, unless its label bears the name
 4 and quantity or proportion of such substance or derivative
 5 and in juxtaposition therewith the statement "Warning--May
 6 be habit-forming";

7 (e) if it is a drug, unless its label bears to the
 8 exclusion of any other nonproprietary name (except the
 9 applicable systematic chemical name or the chemical
 10 formula):

11 (i) the established name (as defined in 50-31-301(1))
 12 of the drug, if such there be; and

13 (ii) in case it is fabricated from two or more
 14 ingredients, the established name and quantity of each
 15 active ingredient, including the kind and quantity or
 16 proportion of any alcohol and also including, whether active
 17 or not, the established name and quantity or proportion of
 18 any bromides, ether, chloroform, acetanilid, acetphenetidin,
 19 amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine,
 20 arsenic, digitalis, digitalis glucosides, mercury, ouabain,
 21 strophanthin, strychnine, thyroid, or any derivative or
 22 preparation of any such substances contained therein;
 23 provided that the requirement for stating the quantity of
 24 the active ingredients, other than the quantity of those
 25 specifically named in this subsection (1)(e)(ii), shall

1 apply only to prescription drugs; provided further that, to
 2 the extent that compliance with the requirements of this
 3 subsection (1)(e)(ii) is impracticable, exemptions shall be
 4 allowed under regulations promulgated by the department or
 5 under the federal act;

6 (f) unless its labeling bears:

7 (i) adequate directions for use; provided that, where
 8 any requirement of this subsection (1)(f)(i), as applied to
 9 any drug or device, is not necessary for the protection of
 10 the public health, the department shall promulgate
 11 regulations exempting such drug or device from such
 12 requirements; provided further that articles exempted under
 13 regulations issued under section 502(f) of the federal act
 14 may also be exempt; and

15 (ii) such adequate warnings against use in those
 16 pathological conditions or by children where its use may be
 17 dangerous to health, or against unsafe dosage or methods or
 18 duration of administration or application, in such manner
 19 and form as are necessary for the protection of users;

20 (g) if it purports to be a drug the name of which is
 21 recognized in an official compendium, unless it is packaged
 22 and labeled as prescribed therein; provided that the method
 23 of packing may be modified with the consent of the
 24 department or if consent is obtained under the federal act.
 25 Whenever a drug is recognized in both the United States

1 Pharmacopoeia and the Homeopathic Pharmacopoeia of the
 2 United States, it shall be subject to the requirement of the
 3 United States Pharmacopoeia with respect to packaging and
 4 labeling unless it is labeled and offered for sale as a
 5 homeopathic drug, in which case it shall be subject to the
 6 provisions of the Homeopathic Pharmacopoeia of the United
 7 States and not to those of the United States Pharmacopoeia;
 8 provided further that, in the event of inconsistency between
 9 the requirements of this subsection and those of subsection
 10 (e) as to the name by which the drug or its ingredients
 11 shall be designated, the requirements of subsection (e)
 12 shall prevail.

13 (n) if it has been found by the department or under
 14 the federal act to be a drug liable to deterioration, unless
 15 it is packaged in such form and manner and its label bears a
 16 statement of such precautions as the regulations issued by
 17 the department or under the federal act require as necessary
 18 for the protection of public health. No such regulation
 19 shall be established for any drug recognized in an official
 20 compendium until the department shall have informed the
 21 appropriate body charged with the revision of such
 22 compendium of the need for such packaging or labeling
 23 requirements and such body shall have failed within a
 24 reasonable time to prescribe such requirements.

25 (i) if it is a drug and its container is so made,

1 formed, or filled as to be misleading;

2 (j) if it is an imitation of another drug;

3 (k) if it is offered for sale under the name of
4 another drug;

5 (l) if it is dangerous to health when used in the
6 dosage or with the frequency or duration prescribed,
7 recommended, or suggested in the labeling thereof;

8 (m) if it is, purports to be, or is represented as a
9 drug composed wholly or partly of insulin, unless:

10 (i) it is from a batch with respect to which a
11 certificate or release has been issued pursuant to section
12 506 of the federal act; and

13 (ii) such certificate or release is in effect with
14 respect to such drug;

15 (n) if it is, purports to be, or is represented as a
16 drug composed wholly or partly of any kind of penicillin,
17 streptomycin, chlortetracycline, chloramphenicol,
18 bacitracin, any other antibiotic drug, or any derivative
19 thereof, unless:

20 (i) it is from a batch with respect to which a
21 certificate or release has been issued pursuant to section
22 507 of the federal act; and

23 (ii) such certificate or release is in effect with
24 respect to such drug; provided that subsection (l)(n) shall
25 not apply to any drug or class of drugs exempted by

1 regulations promulgated under section 507(c) or (d) of the
2 federal act;

3 (o) if it is a color additive, the intended use of
4 which in or on drugs is for the purpose of coloring only,
5 unless its packaging and labeling are in conformity with
6 such packaging and labeling requirements applicable to such
7 color additive prescribed under the provisions of 50-31-108
8 or of the federal act;

9 (p) in the case of any prescription drug distributed
10 or offered for sale in this state, unless the manufacturer,
11 packer, or distributor thereof includes in all
12 advertisements and other descriptive printed matter issued
13 or caused to be issued by the manufacturer, packer, or
14 distributor with respect to that drug a true statement of:

15 (i) the established name, as defined in 50-31-301(1);

16 (ii) the formula showing quantitatively each ingredient
17 of such drug to the extent required for labels under section
18 502(e) of the federal act; and

19 (iii) such other information in brief summary relating
20 to side effects, contraindications, and effectiveness as
21 shall be required in regulations issued under the federal
22 act;

23 (q) if a trademark, trade name, or other identifying
24 mark, imprint, or device or another or any likeness of the
25 foregoing has been placed thereon or upon its container with

1 intent to defraud.

2 (2) A drug which is subject to 50-31-307 shall be
3 deemed to be misbranded if, at any time prior to dispensing,
4 its label fails to bear the statement "Caution: Federal Law
5 Prohibits Dispensing Without Prescription", or "Caution:
6 State Law Prohibits Dispensing Without Prescription". A
7 drug to which 50-31-307 does not apply shall be deemed to be
8 misbranded if, at any time prior to dispensing, its label
9 bears the caution statement quoted in the preceding
10 sentence."

11 SECTION 3. EFFECTIVE DATE. THIS ACT IS EFFECTIVE
12 JANUARY 1, 1980.

-End-

HOUSE OF REPRESENTATIVES

March 14, 1979

Committee of the Whole Amendment to Senate Bill No. 377, third reading copy, as follows:

1. Page 2, line 25.

Following: "manufacturer"

Strike: "as well as the"

Following: "packer"

Insert: ", "

Following: "distributor"

Strike: "IF"

2. Page 3, line 1.

Strike: "DIFFERENT THAN THAT OF THE MANUFACTURER"

Insert: ", except that a prescription drug must contain the name and place of business of the manufacturer as well as the packer or distributor"

AND AS AMENDED,
BE CONCURRED IN