SENATE BILL NO. 365

INTRODUCED BY HAZELBAKER, NORMAN

IN THE SENATE

February	4, 1981	Introduced and referred to Committee on Public Health, Welfare and Safety.
February	11, 1981	Committee recommend bill do pass as amended. Report adopted.
Pebruary	12, 1981	Bill printed and placed on members' desks.
February	13, 1981	Second reading, do pass.
February	14, 1981	Correctly engrossed.
February	16, 1981	Third reading, passed. Ayes, 46; Noes, 0. Transmitted to House.
		IN THE HOUSE
February	17, 1981	Introduced and referred to Committee on Business and Industry.
March 6,	1981	Committee recommend bill be concurred in. Report adopted.
March 9,	1981	Second reading, concurred in.
March 11,	1981	Third reading, concurred in. Ayes, 95; Noes, 0.
		IN THE SENATE

March 12, 1981

Returned from House. Concurred in. Sent to enrolling.

Reported correctly enrolled.

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LC 1255/01

General BILL NO. 365 2 INTRODUCED BY 3 A STLE FOR AN ACT ENTITLED: "AN ACT TO REQUIRE A CODE 4 5 TMPRINT ON CERTAIN DRUGS AS A MEANS OF IDENTIFICATION: PROVIDING FOR ACMINISTRATION BY THE BOARD OF PHARMACISTS; 6 7 AMENDING SECTIONS 50-31-301 AND 50-31-506, MCA: PROVIDING A 8 DELAYED EFFECTIVE DATE." 9 10 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA: Section 1. Section 50-31-301, MCA, is amended to read: 11 12 #50-31-301. Definitions. As used in this part, the 13 following definitions apply:

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

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

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

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

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

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

(3) "Manufacturer" means a person who mixed the final 13 ingredients and prepared the final drug product. 14

15 (4) "Code_ imprint" means_a_series_of_letters_or 16 numbers assigned by the manufacturer or distributor to a 17 specific drug, marks or monograms unique to the manufacturer 18 or distributor of the druge or bothe

(5) "Distributor" means a person who distributes for 19

20 resale a drug in solid dosace form under his own label

21 whether or not he is the manufacturer of the drug.

(6) "Solid dosage form" means capsules or tablets 22

23 intended for oral use.

24 (7) "Legend drug" means any drug_defined_by_section

503(b) of the federal Food: Drug and Cosmetic Act. as 25

> ___ INTRODUCED BILL SB 365

1 amended_on_danuary_15*_1980*_under_which_its_label_is
2 required_to_bear_the_statement:_"Caution:_Federal_law
3 prohibits_dispensing_without_prescription*"*

4 <u>NEW_SECTION</u>. Section 2. Code imprint required on 5 legend drugs. No legend drug in solid dosage form may be 6 manufactured or distributed in this state unless it is 7 clearly marked or imprinted with a code imprint identifying 8 the drug and the manufacturer or distributor of the drug.

9 NEW_SECTION. Section 3. Exemptions from code imprint 10 requirement. The board of pharmacists may grant exemptions 11 from the requirements of [sections 2 and 4] upon a showing 12 by a drug manufacturer or distributor that size, physical 13 characteristics, or other compelling reasons render application of a code imprint on a legend drug subject to 14 15 the provisions of [section 2] impractical or impossible. Any 16 exemption granted must be included in the list required by 17 [section 4] and must describe the physical characteristics 18 and type of drug covered by the exemption.

19 <u>NEW_SECTION</u> Section 4. List of code imprints to be 20 provided. Upon crequest of the board of pharmacists, all 21 manufacturers and distributors of legend drugs in solid 22 dosage form who produce or distribute legend drugs in 23 Montana must provide and keep current a list of those drugs, 24 which list identifies the manufacturer and the specific type 25 of each drug by code imprint. Section 5. Section 50-31-506, MCA, is amended to read: 50-31-506. Penalties. (1) Any person who violates any of the provisions of 50-31-204. <u>[section 2.or.4]</u>, 50-31-501, 50-31-502, or 50-31-208 shall-be is guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 3 months, a fine of not more than \$250, or both such imprisonment and fine.

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

13 Section 6. Codification instruction. Sections 2
14 through 4 are intended to be codified as an integral part of
15 Title 50, chapter 31, part 3, and the provisions of Title
16 50, chapter 31, parts 3 and 5, apply to sections 2 through
17 4.

18 Section 7. Effective date. This act is effective 19 January 1, 1983.

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Approved by Committee on Public Health, safety and Welfare SENATE BILL NO. 365 INTRODUCED BY HAZELBAKER, NORMAN A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE A CODE IMPRINT ON CERTAIN DRUGS AS A MEANS OF IDENTIFICATION; PROVIDING FOR ADMINISTRATION BY THE BOARD OF PHARMACISTS; AMENDING SECTIONS 50-31-301 AND 50-31-506, MCA; PROVIDING A DELAYED 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 following definitions apply: [1] "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

l	labeled-and-offered-for-sale-as-a-ho meopathic-drug v-in-which
2	casetheofficialtitleusedintheHomeopathic
3	Phormocoposia-shall-apply;
4	<pre>(c) if neither subsection (1)(a) nor (1)(b) of this</pre>
5	section applies, then the common or usual name, if any, of
6	such drug or of such ingredient.
7	(2) "Antibiotic drug" means any drug intended for use
8	by man containing any quantity of any chemical substance
9	which is produced by a microorganism and which has the
10	capacity to inhibit or destroy microorganisms in dilute
11	solution (including the chemically synthesized equivalent of
12	any such substance).
13	(3) "Manufacturer" means a person who mixed the final
14	ingredients and prepared the final drug product.
15	(4) "Code_imprint" means a series of letters or
16	<u>numbers assigned by the manufacturer or distributor to a</u>
17	<u>specific drugs marks or monograms unique to the manufacturer</u>
18	<u>or distributor of the drug, or both.</u>
19	(5) "Distributor" means a person who distributes for
20	<u>resale a drug in solid dosage form under his own label</u>
21	whether or not he is the manufacturer of the drug.
22	(6) "Solid_dosage_form"_means_capsules_or_tablets
23	intended for oral_use.
24	[7] "Legend_drug" means any drug_defined_by_section
25	203(b) of the federal Food, Drug and Cosmetic Act, as

-2- SECOND READEING

1 amended on January 15, 1980, under which its label is 2 required to bear the statement: "Caution: Federal law 3 prohibits dispensing without prescription.""

4 <u>NEW SECTION</u>. Section 2. Code imprint required on 5 legend drugs. No legend drug in solid dosage form may be 6 manufactured or distributed in this state unless it is 7 clearly marked or imprinted with a code imprint identifying 8 the drug and the manufacturer or distributor of the drug.

Э NEW SECTION. Section 3. Exemptions from code imprint 10 requirement. The board of pharmacists may grant exemptions 11 from the requirements of [sections 2 and 4] upon a showing 12 by a drug manufacturer or distributor that size, physical 13 characteristics, or other compelling reasons render application of a code imprint on a legend drug subject to 14 15 the provisions of [section 2] impractical or impossible. Any exemption granted must be included in the list required by 16 17 [section 4] and must describe the physical characteristics 18 and type of drug covered by the examption.

19 <u>NEW SECTION</u>. Section 4. List of code imprints to be 20 provided. Upon request of the board of pharmacists, all 21 manufacturers and distributors of legend drugs in solid 22 dosage form who produce or distribute legend drugs in 23 Montana must provide and keep current a list of those drugs, 24 which list identifies the manufacturer and the specific type 25 of each drug by code imprint. Section 5. Section 50-31-506. MCA, is amended to read: "50-31-506. Penalties. [1] Any person who violates any of the provisions of 50-31-204. [section 2 or 4], 50-31-501. 50-31-502. or 50-31-208 shall-be is guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 3 months, a fine of not more than \$250, or both such imprisonment and fine.

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

Section 6. Codification instruction. Sections 2
through 4 are intended to be codified as an integral part of
Title 50, chapter 31, part 3, and the provisions of Title
50, chapter 31, parts 3 and 5, apply to sections 2 through
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. . 1 labeled-and-offered-for-sale-as-a-homeopathic-drucy-in-which 1 SENATE BILL NO. 365 ease---the---official----title---used---in---the--Homeopothic 2 INTRODUCED BY HAZELBAKER, NORMAN г з Phormacopoeia-shall-apply: 3 4 (c) if neither subsection (1)(a) nor (1)(b) of this A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE. A CODE 4 5 section applies, then the common or usual name, if any, of IMPRINT ON CERTAIN DRUGS AS A MEANS OF IDENTIFICATION: 5 such drug or of such ingredient. 6 PROVIDING FOR ADMINISTRATION BY THE BOARD OF PHARMACISTS: 6 (2) "Antibiotic drug" means any drug intended for use 7 AMENDING SECTIONS 50-31-301 AND 50-31-506. MCA: PROVIDING A 7 8 by man containing any quantity of any chemical substance DELAYED EFFECTIVE DATE." 8 9 which is produced by a microorganism and which has the 9 . BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA: 10 capacity to inhibit or destroy microorganisms in dilute 10 11 solution (including the chemically synthesized equivalent of Section 1. Section 50-31-301, MCA, is amended to read: 11 12 any such substance). 12 "50-31-301. Definitions. As used in this part, the 13 (3) "Manufacturer" means a person who mixed the final 13 following definitions apply: ingredients and prepared the final drug product. (1) "Established name", with respect to a drug or 14 14 15 (4) "Code imprint" means a series of letters or 15 ingredient thereof, means: numbers assigned by the manufacturer or distributor to a (a) the applicable official name designated pursuant 16 18 17 specific drugt marks or monograms unique to the manufacturer 17 to section 508 of the federal act: 18 or distributor of the drug, or both. (b) if there is no such name and such drug or such 18 19 (5) "Distributor" means a person who distributes for ingredient is an article recognized in an official 19 20 resale a drug in solid dosage form under his own label compendium, then the official title thereof in such 20 21 compendium; or provided that, where subsection (1)(a) of 21 whether or not he is the manufacturer of the drug. 22 (6) "Solid dosage form" means capsules or tablets this section applies to an article recognized in the United Z2 23 intended for oral use. 23 States Pharmacopoeia and in-the-Homeopathic--Pharmacopoeia (7) "Legend drug" means any drug defined by section 24 under different official titles, the official title used in 24 25 503(b) of the federal Food, Drug and Cosmetic Act, as 25 the United States Pharmacopoeia shall apply unless--it--is

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1	Section 5. Section 50-31-506, MCA, is amended to read:
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3	of the provisions of 50-31-204, [section 2 or 4], 50-31-501.
4	50-31-502, or 50-31-208 shall-be is guilty of a misdemeanor
5	and shall on conviction thereof be subject to imprisonment
6	for not more than 3 months, a fine of not more than \$250, or
7	both such imprisonment and fine.
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9 of such person under this section has become final, such person shall be subject to imprisonment for not more than b 10 11 months, a fine of not more than \$500, or both such 12 imprisonment and fine."

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2	INTRODUCED BY HAZELBAKER+ NORMAN	2	casetheofficialtitleusedintheHomeopathic
3		3	Pharmacopoeta-shall-apply;
4	A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE A CODE	4	(c) if neither subsection (1)(a) nor (1)(b) of this
5	IMPRINT ON CERTAIN DRUGS AS A MEANS OF IDENTIFICATION;	5	section applies, then the common or usual name, if any, of
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14	(1) "Established name", with respect to a drug or	14	ingredients and prepared the final drug product.
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17	to section 508 of the federal act;	17	specific drug, marks or monograms unique to the manufacturer
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21	compendium; or provided that, where subsection (1)(b) of	21	whether or not he is the manufacturer of the drug.
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24	under different official titles, the official title used in	24	(7) "Legend drug" means any drug defined by section
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			-2- \$8 365

REFERENCE BILL

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SB 365

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-End-

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