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.
February 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.

INTRODUCED BY Senator Gilbert Norman BILL NO. 365

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 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) "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 mixed the final ingredients and prepared the final drug product.

(4) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, marks or monograms unique to the manufacturer or distributor of the drug, or both.

(5) "Distributor" means a person who distributes for resale a drug in solid dosage form under his own label whether or not he is the manufacturer of the drug.

(6) "Solid dosage form" means capsules or tablets intended for oral use.

(7) "Legend drug" means any drug defined by section 503(b) of the federal Food, Drug and Cosmetic Act, as

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

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

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

NEW SECTION. Section 4. List of code imprints to be provided. Upon request of the board of pharmacists, all manufacturers and distributors of legend drugs in solid dosage form who produce or distribute legend drugs in Montana must provide and keep current a list of those drugs, which list identifies the manufacturer and the specific type 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.

(2) If the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than 6 months, a fine of not more than $500, or both such 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 4.

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

-End-

Approved by Committee on Public Health, Safety and Welfare

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SECOND READING

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