HB BILL NO. 219

INTRODUCED BY Conroy

A BILL FOR AN ACT ENTITLED: "AN ACT TO CONTROL THE DISTRIBUTION OF SAMPLE DRUGS."

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

Section 1. Purpose. It is the purpose of this act to control the distribution of sample drugs which are used by manufacturers thereof for promotional or advertising purposes.

Section 2. Definitions. In this act the following definitions apply:

(1) "Board" means the board of pharmacists provided for in 82A-1602.21.

(2) "Brand name" means the proprietary or registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

(3) "Generic name" means the chemical or established name of a drug product or drug ingredients published in the latest edition of the official United States pharmacopoeia or official homeopathic pharmacopoeia of the United States.

(4) "Prescription drug" means a drug which under 27-716, 54-322, the Federal Food, Drug, and Cosmetic Act (21 USC 301 et. seq.), or any other applicable law may be dispensed only upon prescription of a person licensed to administer such drug.

(5) "Sample drug" means a prescription drug which is distributed free of charge for promotional or advertising purposes.

Section 3. Distribution of samples — written request required. (1) No manufacturer may, directly or indirectly, distribute any sample drug except upon the written request of a person licensed to administer or dispense that drug.

(2) Such request shall contain:

(a) the name and address of the manufacturer;

(b) the name and address of the person making the request;

(c) the brand name of the drug;

(d) the generic name of the drug; and

(e) if the drug is a compound or mixture, the generic name of each ingredient and its strength in milligrams per dosage unit.

(3) Such written request may be made effective for no more than 1 year.

Section 4. Requests to be preserved — inspection. All requests referred to in [section 3] shall be preserved by the manufacturer for at least 2 years and shall, during regular business hours, be open to inspection by the board.

LC 0637/01

Section 5. Rule-making power. The board may adopt rules for the proper administration of this act.

Section 6. Powers and duties of board. (1) The board may initiate such investigations and inspections as it considers necessary to carry out the purpose of this act.

(2) The board shall report each violation of this act to the appropriate county attorney who shall initiate appropriate proceedings.

Section 7. Penalty. A person, corporation, partnership, or association violating this act is guilty of a misdemeanor.

-End-

STATE OF MONTANA

REQUEST NO. 105-77

FISCAL NOTE

Form BD-15

In compliance with a written request received January 19, 19 77, there is hereby submitted a Fiscal Note for House Bill 219 pursuant to Chapter 53, Laws of Montana, 1965 - Thirty-Ninth Legislative Assembly.

Background information used in developing this Fiscal Note is available from the Office of Budget and Program Planning, to members of the Legislature upon request.

DESCRIPTION OF PROPOSED LEGISLATION:

An act to control the distribution of sample drugs.

ASSUMPTION:

Travel for staff would increase to allow for two (2) out-of-town inspection trips per month.

FISCAL IMPACT:

	FY 78	FY 79
Proposed Law:		
Operating Expense	$17,027	$18,504
Expenditures under current law	16,327	17,804
Increased expenditures under proposed law:	$ 700	$ 700

LONG-RANGE EFFECTS:

Violations of proposed bill could result in costly hearings and court costs.

Richard L. Dunn for

BUDGET DIRECTOR

Office of Budget and Program Planning

Date: 1-21-77

Approved by Committee
on Public Health,Welfare
& Safety

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March 8, 1977

STANDING COMMITTEE REPORT
Senate Committee on Public Health, Welfare & Safety

That House Bill No. 219 be amended as follows:

1. Amend page 2, section 3, line 10.
Following: "administer"
Strike: "or dispense"

2. Amend page 2, section 3, line 15.
Following: "drug;"
Insert: "or"

3. Amend page 2, section 3, line 16.
Following: "drug;"
Strike: "and"

4. Amend page 2, section 3, lines 17 through 19.
Following: line 16
Strike: lines 17 through 19 in their entirety

5. Amend page 2, section 4, line 24.
Following: "manufacturer"
Insert: "at its regular place of business"

6. Amend page 3, section 6, line 4.
Following: "and"
Strike: "inspections"
Insert: "searches pursuant to lawful warrant"