FOOD AND DRUGS

CHAPTER 249

HOUSE BILL NO. 1202
(Committee on Industry, Business, and Labor)
(At the request of the State Board of Pharmacy)

DRUG LICENSE OR PERMIT FEE

AN ACT to amend and reenact subsection 15 of section 19-02.1-02 of the North Dakota Century Code, relating to prohibited acts of manufacture and sale of drugs at wholesale or retail without license and payment of license fee.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF THE STATE OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Subsection 15 of section 19-02.1-02 of the 1979 Interim Supplement to the North Dakota Century Code is hereby amended and reenacted to read as follows:

15. The manufacture of drugs, or the supplying of drugs at wholesale or retail, unless a license or permit to do so has first been obtained from the ~~state~~ board of pharmacy after application to the ~~state~~ board of pharmacy and the payment of a ~~licensing~~ fee ~~of not to exceed three dollars~~ set by the board of pharmacy.

Approved February 20, 1981

CHAPTER 250

HOUSE BILL NO. 1400
(Hoffner, Wagner)

CODE IMPRINT ON SOLID DOSAGE DRUGS

AN ACT to amend and reenact section 19-02.1-14.1 of the North Dakota Century Code, relating to definitions, identification, and dispensing of prescription drugs; and to provide an effective date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF THE STATE OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 19-02.1-14.1 of the 1979 Interim Supplement to the North Dakota Century Code is hereby amended and reenacted to read as follows:

19-02.1-14.1. DEFINITIONS - LABEL OF PRESCRIPTION DRUGS - SELECTING AND DISPENSING GENERIC NAME DRUGS - IDENTIFICATION OF PRESCRIPTION DRUGS.

1. As used in this section, unless the subject matter or context otherwise requires:

   a. "Brand name" means the registered trademark name given to a drug or medicine by its manufacturer, labeler, or distributor.

   b. ~~"Generic--name"-means-the-established-name-or-official chemical-name-of-the-drug,-drug-product,-or--medicine.~~ "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both.

   c. ~~"Therapeutically-equivalent"-means-a-generic-name-drug product--that--would--elicit--the---same---therapeutic response--from--the--same--person-as-a-brand-name-drug product.~~ "Distributor" means a person who distributes for resale a drug in solid dosage form under his own label even though he is not the actual manufacturer of the drug.

d. "Generic name" means the established name or official chemical name of the drug, drug product, or medicine.

e. "Prescription drug" means any drug defined by section 503(b) of the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription.".

f. "Solid dosage form" means capsules or tablets intended for oral use.

g. "Therapeutically equivalent" means a generic name drug product that would elicit the same therapeutic response from the same person as a brand name drug product.

2. Drugs or medicines dispensed pursuant to a prescription shall bear a label permanently affixed to the immediate container in which the drug or medicine is dispensed and which is received by the purchaser. The label shall bear the brand name or the generic name and strength of the drug or medicine, except when the physician or other health care provider authorized by law to prescribe drugs or medicine has notified the pharmacist that the appearance of the name on the label would be alarming to or detrimental to the well-being of the purchaser of the prescription.

3. The form for a written prescription shall have two signature lines at opposite ends of the bottom of the form. Under the line on the right side shall be clearly printed the words "dispense as written". Under the line on the left side shall be clearly printed the words "substitution permitted". The physician shall communicate his instructions to the pharmacist by signing the appropriate line. If an oral prescription for a brand name drug product is given to a pharmacist, the practitioner shall instruct the pharmacist as to whether the drug must be dispensed as prescribed or whether a therapeutically equivalent generic name drug product may be substituted in its place. The pharmacist shall note the instructions on the file copy of the prescription. The pharmacist shall not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist shall not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to the effective date of this

subsection, determined to be therapeutically equivalent, then the previously mentioned substitution ban shall be automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription shall include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the Federal Social Security Act, the following shall also apply:

   a. If the practitioner has signed the appropriate line of a prescription instructing the pharmacist to dispense as written, the words "brand necessary" must also be written on the prescription in the practitioner's own handwriting. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten instruction does not appear on the prescription.

   b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription. The prescription shall then be signed by the practitioner on the appropriate line and the words "brand necessary" must also be written on the prescription in the practitioner's own handwriting.

5. A pharmacist may not select and dispense a ~~generic name~~ different drug product for a prescribed drug product unless it has been manufactured with the following minimum manufacturing standards and practices by a manufacturer who:

   a. Marks capsules and tablets with identification code or monogram.

   b. Labels products with their expiration date.

   c. Provides reasonable services to accept return goods that have reached their expiration date.

d. Provides the pharmacist with information from which it can be determined whether a drug product is therapeutically equivalent.

e. Maintains recall capabilities for unsafe or defective drugs.

6. No prescription 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.

7. All manufacturers and distributors of prescription drugs in solid dosage form shall provide to the department, upon request, a listing of all such prescription drugs identifying by code imprint the manufacturer and the specific type of drug. The listing shall at all times be kept current by all manufacturers and distributors subject to the provisions of this section.

8. The department may grant exemptions from the requirements of this section upon application by any drug manufacturer or distributor which shows size, physical characteristics, or other unique characteristics of a drug that render the use of a code imprint on the drug impractical or impossible. Any exemption granted by the department shall be included by the manufacturer or distributor in the listing required by this section. The listing shall describe the physical characteristics and type of drug to which the exemption relates.

9. All prescription drugs in solid dosage form that are possessed, distributed, sold, or offered for sale in violation of the provisions of this section shall be deemed misbranded and shall be seized by the department.

SECTION 2. EFFECTIVE DATE. This Act shall become effective on January 1, 1982.

Approved March 16, 1981