6800.4050 DRUG IDENTIFICATION.

Subpart 1. **Minimum requirement.** The finished dosage form of any legend drug in solid oral dosage form manufactured, packaged, or distributed for sale in this state after January 1, 1983, shall be clearly marked or imprinted with a symbol, number, name, word, letter, national drug code number, or other mark identifying the drug and the manufacturer or distributor of the drug.

Subp. 2. **Imprints.** Each manufacturer and distributor shall publish and provide to the board printed material which will identify each imprint or mark currently used by the manufacturer or distributor. The board shall also be notified of any changes in the published list.

Subp. 3. **Exemptions.** Drug manufacturers, packagers, or distributors seeking an exemption from the requirements of subpart 1 or 2 shall submit to the board a documentation of facts related to the product which would make impractical compliance with the imprinting required by Minnesota Statutes, section 151.361, subdivision 2. The documentation must include specifics on the physical characteristics of the drug upon which the exemption request is based.

Statutory Authority: *MS s 152.02*

History: *9 SR 1656*

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