

10284 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-550-8464 (P. D. No. 7)

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

- (a) the item name designated as
"MEPROBAMATE TABLETS, U.S.P."
- (b) the quantity of active ingredient designated as
"0.4 Gram"
- Note: The official abbreviation "g." may be used in lieu of "gram."
- (c) the phrase "500 tablets" or a similar phrase
- (d) the Federal Stock No.
- (e) the lot or control number
- (f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

- (g) the date of manufacture
- (h) the recommended dosage
- (i) the statement "Caution: Federal law prohibits dispensing without prescription."

Unit packages. Each unit package label shall bear the same information as required for the label of the immediate container.

A circular, brochure, or other printed matter shall be packaged within each unit package setting forth as a minimum: Indications; Recommended dosage; Contraindications; Side Reactions, and Toxicity.