

10410 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-890-2010 (P. D. No. 3)

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

5.2.1 Immediate containers.

5.2.1.1 For FSN 6505-890-2010. Each immediate container label for FSN 6505-890-2010 shall bear the following information. However, the information is not required to appear in the sequence indicated.

- (a) the item name designated as
"PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC
FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP"
- (b) the quantity of contents designated as
"1 gal (3.78 liters)"
- (c) the quantity of active ingredients expressed in
milligrams or minims per 5 cc (one teaspoonful)
- (d) the Federal Stock No. designated as
"FSN 6505-890-2010" or "Stock No. 6505-890-2010"
- (e) the lot or control number
- (f) the date of manufacture
- (g) 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.
- (h) the statement "Caution: Federal law prohibits
dispensing without prescription."
- (i) the following or similar statements:
 - 1. Keep tightly closed.
 - 2. Protect from light.
 - 3. Shake well.
- (j) the statement "Store at controlled room temperature
(59° - 86° F.)."