6505-116-9325 (P. D. #3)

All ingredients entering into the finished capsules shall be of U.S.P. or N.F. quality or, if not included in either of these compendia, the ingredients shall be of the highest pharmaceutical grade.

Not more than 6 months shall have elapsed from the date of manufacture of the product to the date of delivery to the Government.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1 or 2

CLOSURE A, B, or F SEAL A or B

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.

FSN 6505-116-9325

Each immediate container label for FSN 6505-116-9325 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "SODIUM DIPHENYLHDANTOIN CAPSULES, U.S.P."

(b) the quantity of active ingredient designated as "100 mg"

(c) the phrase "100 capsules" or a similar phrase

(d) the stock number designated as "FSN 6505-116-9325" or "Stock No. 6505-116-9325"

(e) the lot or control number

(f) the statement "Caution: Federal law prohibits dispensing without prescription."

(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 date of manufacture