10356 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

[•		20 Pebruary 1969	
	FEDERAL STOCK HO.	ITEM IDENTIFICATION	UHIT	
1	6505-138-4225	PROPYLTHIOURACIL TABLETS, USP, 50 mg, 100s	Bottle	

Shall be Promylthiouracil Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 110a, dated 30 October 1966, together with the options and additions stated herein:

- S2. Classification. Shall be type I, class 1.
- S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 50 mg of Propylthiouracil per tablet, within the applicable assay limits for the tablets.

The Propylthiouracil used in the manufacture of the tablets shall meet the tests, standards, and requirements of the U.S.P., except that the U.S.P. limit of heavy metals shall be modified to read "not more than 10 parts per million."

The Propylthiouracil powder shall comply with the maximum limit for "Thiourea" as given in the British Pharmacopoeia, 1968, pages 8.6 and 62h.

S6.4.2 Color. Uncoated tablets shall be white.

S6.h.7 Scoring. Tablets shall be scored.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-185, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A JLASS 1

TYPE e

STYLE 2 GRADE 1

CLOSURE A, B, F, or G

SEAL A or B (for closures A, B, and F only)

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

(See labeling on page 2)

32-814 592

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OPSC FORM 2087

REPLACES OMSC FORM T-4120/11; MAR 64, WHICH WILL BE USED UNTIL DEPLETED