

**NDA 06-188
PROPYLTHIOURACIL TABLETS, USP**

Antithyroid

**DAVA Pharmaceuticals, Inc.
Parker Plaza
400 Kelby Street, 10th Floor
Fort Lee, NJ 07024
Quality Assurance 1-877-963-8422**

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of PROPYLTHIOURACIL tablets.

II. REMS ELEMENTS:

A. Medication Guide

In accordance with 21 CFR 208.24, DAVA Pharmaceuticals Inc. will ensure the currently approved Medication Guide is dispensed with each propylthiouracil prescription.

Propylthiouracil is sold in bottles of 100's and 1000's. Each carton contains 24 bottles of 100's and 12 bottles of 1000's. Presuming the smallest patient prescription dose of 30 tablets, in order to insure enough Medication Guides are available for distribution to patients, cartons of 100's will include one (1) pad of 100 each. Cartons of 1000's will include eight (8) pads of 100 each. DAVA Pharmaceuticals' packaging records will be revised to reflect this addition.

DAVA will ensure that the label of each container includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed; i.e. "Dispense the accompanying Medication Guide to each patient."

B. Timetable for Submission of Assessments

DAVA Pharmaceuticals, Inc. will submit REMS Assessments to the FDA by 18 months, 3 years and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than sixty (60) days before the submission date for that assessment. DAVA Pharmaceuticals, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.