DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 006188/S-024

**SUPPLEMENT APPROVAL**

Vintage Pharmaceuticals, LLC d/b/a Qualitest Pharmaceuticals
Agent for DAVA Pharmaceuticals, Inc.
Attention: Bernadette Attinger
Director Regulatory Affairs
7 Clarke Drive
Cranbury, NJ 08512

Dear Ms. Attinger:

Please refer to your Supplemental New Drug Application (sNDA) dated September 10, 2013, received September 11, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Propylthiouracil tablets.

We also refer to our letter dated May 16, 2013, requesting that changes in the **ADVERSE REACTIONS** section of the Package Insert (PI) be made so as to furnish adequate information for the safe and effective use of the drug.

This sNDA provides for revisions to the labeling for Propylthiouracil consistent with our May 16, 2013, supplement request letter.

In addition, revisions to the PI include the following:

- Under **DOSAGE AND ADMINISTRATION**, **Adults** subsection, duplicate text was removed, as the identical text already appears in the **Geriatric Patients** subsection.

- Under **HOW SUPPLIED**, Propylthiouracil tablets engraved "LL" was removed as it is no longer available

The sNDA also provides for the following revisions to both the PI and the Medication Guide:

- Under **DESCRIPTION**, the Component name "modified food starch" was updated to "pregelatinized starch"

- A new manufacturing site, [redacted] (b) (4) (approved September 17, 2013 in S-023), was added

## APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below and reflected in the enclosed labeling.

- Revision dates changed to reflect the date of approval for this supplement

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf .

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

Sincerely,

*{See appended electronic signature page}*

Jean-Marc Guettier, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Package Insert
Medication Guide

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JEAN-MARC P GUETTIER
02/10/2015