DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-856

Food and Drug Administration
Rockville MD 20857

JUN 28 2006

Vintage Pharmaceuticals, LLC
Attention: Sam E. Kleiner
Manager, Regulatory Affairs
150 Vintage Drive
Huntsville, AL 35811

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 23, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clonazepam Tablets USP, 0.5 mg, 1 mg and 2 mg.

Reference is also made to your amendments dated February 3, March 24, May 11, May 25, and June 7, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Clonazepam Tablets USP, 0.5 mg, 1 mg and 2 mg, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Klonopin Tablets, 0.5 mg, 1 mg, and 2 mg, respectively, of Hoffmann LaRoche, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Lee Test /for

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research