DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-171

AUG 3 2005

Kali Laboratories, Inc.
Attention: Scott Groner
400 Campus Drive
Somerset, NJ 08873

Dear Sir:

This is in reference to your abbreviated new drug application dated June 1, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Clonazepam Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg.

Reference is also made to your amendments dated November 19, 2004 and March 21, March 23, May 9, July 25, and July 26, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Clonazepam Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Klonopin Rapidly Disintegrating Tablets of Hoffmann La Roche, 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 abbreviated application require an approved supplemental application before the change may be made.

Post marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

FDA's field staff has not completed the validation of the regulatory methods submitted in your application. It is the policy of the Office of Generic Drugs to proceed with approval of your application while this process continues. We acknowledge receipt of your commitment to cooperate with the agency to resolve any methods validation related deficiencies which may be identified.

Sincerely yours,

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