DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-171/S-006

PAR Pharmaceutical Inc.
Attention: Linda Kulick
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your supplemental new drug application dated May 22, 2009, submitted pursuant to 21 CFR 314.70(c)(6) "Supplement - Changes Being Effected" regarding your abbreviated new drug application for Clonazepam Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 2 mg.

We also refer you to the Complete Response letter issued by the Agency on October 30, 2009.

In our letter of October 30th, we requested that you include warning statements in your labeling regarding the inactive ingredient, aspartame. However, as you correctly pointed out in a telephone call to the Agency, the statement is already contained in the labeling. Therefore, your labeling submitted May 22, 2009 is approved. This letter supersedes the Complete Response letter issued October 30, 2009.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

William Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77171	SUPPL-6	KALI LABORATORIES INC	CLONAZEPAM

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

/s/

LILLIE D GOLSON
12/07/2009
for Wm. Peter Rickman