



ANDA 77-827/S-001

Kali Laboratories, Inc
Attention: Laya Steve
120 Belmont Drive
Somerset, NJ 08873

Dear Madam:

This is in reference to your supplemental new drug application dated July 3, 2007 submitted pursuant to 21 CFR 314.70(c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug applications for Oxandrolone Tablets USP, 2.5 mg and 10 mg.

The supplemental application provides for revised package insert.

We have completed the review of this supplemental application and it is approved.

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}

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

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

/s/

John Grace
12/31/2007 11:17:46 AM
for Wm Peter Rickman