DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 71-297/S-026

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your supplemental new drug application dated August 23, 2007, submitted pursuant to 21 CFR 314.70(c)(6)(Supplement - Changes Being Effected) regarding your abbreviated new drug application for Chlordiazepoxide and Amitriptyline Hydrochloride Tablets USP, 5 mg/12.5 mg and 10 mg/25 mg.

The supplemental applications provide for revisions to the package insert labeling to be in accordance with class labeling revisions regarding suicidality and revisions to the Medication Guide pertaining to pediatric suicidality.

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
2/20/2008 12:19:24 PM
for Wm Peter Rickman