DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 71-297/S-025

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 June 13, 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 application provides for revisions to the package insert labeling to be in accordance with class labeling revisions for the addition of a boxed warning and other changes to product labeling and the addition of a medication Guide pertaining to pediatric suicidality.

We have completed the review of this supplemental application and it is approved. However at the time of next printing, please make the following revision. The revised labeling may be submitted to an annual report provided the changes are described in full.

PRECAUTIONS

Relocate the "Information for Patients" subsection to appear after the "General" subsection. We refer you to 21 CFR 201.57(f) for the proper ordering of subsections in this section.

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
7/11/2007 07:34:33 PM
for Wm Peter Rickman