DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 075417/S-021, S-024, and S-025

Mylan Pharmaceuticals Inc.
Attn: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your supplemental new drug applications dated October 27, 2008 and May 13, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clozapine Tablets USP, 25 mg and 100 mg.

Reference is also made to your amendments dated December 3, 2008; and November 25, and December 11, 2009. Reference is also made to your ANDA suitability petitions submitted under Section 505(j)(2)(c) of the Act and approved on February 17, 2000 and November 26, 2002. These petitions permitted you to submit these supplemental ANDAs for a drug product that differs in strength (total drug content) from that of the reference listed drug product. Specifically, Clozaril Tablets USP, of Novartis is supplied as 25 mg and 100 mg strength tablets. You have requested approval for 12.5 mg, 50 mg, and 200 mg strength tablets.

These supplemental applications submitted as “Prior Approval Supplements,” provide for:

S-021: The addition of 12.5 mg and 200 mg dose strengths and labeling revisions associated with the new strengths.

S-024: The addition of the 50 mg dose strength.

S-025: The labeling revisions associated with the 50 mg strength.

We have completed the review of these supplemental applications as amended, and have concluded that the new 12.5 mg, 50 mg, and 200 mg strengths of the drug product are safe and effective for use as recommended in the submitted labeling. Accordingly the supplemental ANDAs are approved, effective on the date of this letter. The new strengths of Clozapine Tablets USP, 12.5 mg, 50 mg, and 200 mg, can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA 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
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

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 with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLa

beling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 075417"***.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-75417	SUPPL-25	MYLAN PHARMACEUTICALS INC	CLOZAPINE ORAL SUSPENSION, 50 MG/ML
ANDA-75417	SUPPL-24	MYLAN PHARMACEUTICALS INC	CLOZAPINE ORAL SUSPENSION, 50 MG/ML
ANDA-75417	SUPPL-21	MYLAN PHARMACEUTICALS INC	CLOZAPINE ORAL SUSPENSION, 50 MG/ML

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

/s/

ROBERT L WEST

04/15/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.