DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091001

Mylan Pharmaceuticals Inc.
Attention: 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 abbreviated new drug application (ANDA) dated November 27, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nisoldipine Extended-release Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg.

Reference is also made to your amendments dated February 28, May 4, and May 26 26, 2009; and January 12, January 13, January 25, January 29, August 16, and November 30, 2010. In addition, we acknowledge receipt of your correspondences dated February 20, 2009, and January 12, 2010, addressing the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Nisoldipine Extended-release Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Sular Extended-release Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg, respectively, of Shionogi Pharma. (Shionogi).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Method:

Medium: HCl with Sodium Lauryl Sulfate (SLS) (32.5 ± 0.1g SLS in 6489 mL of purified water containing 17.0 mL HCl, pH adjusted to 1.20 ± 0.05 with HCl)

Volume: 900 mL
Apparatus: II (Paddle)
Speed: 50 rpm

The drug products should meet the following "interim" specifications:

For the 8.5 mg, 25.5 mg and 34 mg strengths:

| Time (hours) | Percent Dissolved |
|---|---|
| 4 | (b) (4) |
| 8 | |
| 15 | |

For the 17 mg strength:

| Time (hours) | Percent Dissolved |
|---|---|
| 4 | (b) (4) |
| 8 | |
| 15 | |

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Shionogi's Sular Extended-release Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,422,123 (the '123 patent) and 5,626,874 (the '874 patent) are scheduled to expire on June 6, 2012, and November 30, 2014, respectively.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that both patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Nisoldipine Extended-release

Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg, under this ANDA. You have notified the agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Mylan within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '123 and '874 patents. Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Nisoldipine Extended-release Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please 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 section 505-1(i) of the Act.

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 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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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

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/s/

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ROBERT L WEST

01/26/2011

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