DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 79-051

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 abbreviated new drug application (ANDA) dated June 8, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nisoldipine Extended-release Tablets, 20 mg, 30 mg and 40 mg.

Reference is also made to your amendments dated August 22, 2007; and January 25, April 14, May 19, and June 24, 2998.

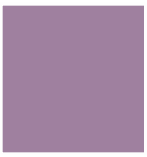
We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Nisoldipine Extended-release Tablets, 20 mg, 30 mg and 40 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Sular Extended-release Tablets, 20 mg, 30 mg and 40 mg, of Sciele Pharma Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. Dissolution Testing should be conducted with the following "interim" method and specifications:

| | |
|---|---|
| Method: | 0.05M (pH 6.8 phosphate buffer containing 1% sodium lauryl sulfate at 37 degrees Celsius |
| Volume: | 900 mL |
| USP Apparatus: | II (Paddle) at 50 rpm |

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

| Time (hours) | Percent Dissolved |
|---|---|
| 1 | |
| 3 | |
| 6 | |
| 12 | |



The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when 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.

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.

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.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler
Director
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/
---
Robert L. West
7/25/2008 10:59:40 AM
Deputy Director, for Gary Buehler