DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019129/S-043

**SUPPLEMENT APPROVAL**

Mylan Pharmaceuticals Inc.
Attention: S. Wayne Talton
President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26505-4310

Dear Mr. Talton:

Please refer to your Supplemental New Drug Application (sNDA) dated February 9, 2011, received February 9, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Maxzide (triamterene/hydrochlorothiazide) 37.5/25 mg and 75/50 mg Tablets and Maxzide-25 (triamterene/hydrochlorothiazide) 37.5/25 mg and 75/50 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for labeling revisions as follows:

1. On the first page of the label, under the name **MAXZIDE** and **MAXZIDE-25**, the generic names were added. The section now reads:

**MAXZIDE® TABLETS**
**(triamterene and hydrochlorothiazide tablets, USP)**
**75 mg/50 mg**
**and**
**MAXZIDE®-25 MG TABLETS**
**(triamterene and hydrochlorothiazide tablets, USP)**
**37.5 mg/25 mg**

**Evaluation& Conclusion:** This revision is consistent with standard formatting and should be approved.

2. Under **DESCRIPTION**, the following was added to the list of inert ingredients:

Maxzide-25 MG tablets also contain FD&C Blue No. 1 Aluminum Lake.

3. Under **WARNINGS**, the following section was added:

**Acute Myopia and Secondary Angle-Closure Glaucoma**
Hydrochlorothiazide, a sulfonamide, can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue hydrochlorothiazide as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

4. The revision date and version number were updated.

5. It is noted that there are multiple editorial revisions (i.e. the word “two” was changed to “2”, the word “four” was changed to “4”, the addition and deletion on hyphens, headings were bolded/unbolded, headings were italicized, and the addition of the USP designation).

There are no other changes from the last approved package insert.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all

changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

**PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Michael Monteleone
Regulatory Project Manager
(301) 796-192

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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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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MARY R SOUTHWORTH
03/20/2011