DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-832/S-002 & S-003

MYLAN PHARMACEUTICALS INC.
Attention: Frank R. Sisto
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, West Virginia 26504-4310

Dear Mr. Sisto:

Please refer to your supplemental new drug applications dated July 22, 1999 (S-002) and August 4, 2000 (S-003), received July 23, 1999 and August 7, 2000, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SULFAMYLON (Mafenide Acetate, USP) For 5% Topical Solution.

We acknowledge receipt of your submission(s) to S-002 dated July 19, 2000 and January 25, 2001 and to S-003 dated January 25, 2001. Your submission of January 25, 2001 constituted a complete response to our February 15, 2000 (S-002) and December 6, 2000 (S-003) action letters.

These supplemental new drug applications provide for the following changes:

1. Supplement 002 – Extends the storage time of the product after reconstitution from the current 48 hours to 28 days.

2. Supplement 003 –Revises the product to a sterile product and provides for revisions to the DESCRIPTION, DOSAGE AND ADMINISTRATION and HOW SUPPLIED sections of the labeling.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and the immediate container and carton labels submitted January 25, 2001) along with the changes provided in the Agency's facsimile of May 25, 2001 and agreed to by Mylan in the facsimile of May 30, 2001.

Please submit the copies of final printed labeling (FPL) electronically to the application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, the submission should be designated "FPL for approved supplements NDA 19-832/S-002/S-003." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Maureen Dillon-Parker, Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Attachment – Fax of May 30, 2001

May-30-2001 03:56pm From- T-138 P.001/001 F-252

MYLAN PHARMACEUTICALS INC
781 Chestnut Ridge Road • P. O. Box 4310 • Morgantown, West Virginia 26504-4310 U.S.A. • (304) 599-2595

FAX COVER

DATE: May 30, 2001

TO: Ms. Maureen Dillon-Parker, Project Manager
Division of Anti-Infective Drug Products
CDER, FDA

FROM: Andrea B. Miller, Director
Regulatory Affairs
Mylan Pharmaceuticals Inc.

RE: SULFAMYLON® (Mafenide Acetate, USP) For 5% Topical Solution
NDA 19-832/S-002 and S-003

Ms. Dillon-Parker,

We acknowledge receipt of your fax dated May 25, 2001 in regard to the above referenced supplemental applications. We agree with the Agency's suggested labeling revisions provided in the fax. Mylan will incorporated these revisions into the final printed labeling.

Please contact me if you have any questions or comments.

Sincerely,

Andrea B. Miller, R.Ph., Esq.

PHONE - (304) 598-5431 Ext. 6869 or 6500
FAX - (304) 285-6407

Number of pages including this sheet 1

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Business Development	(304) 599-7284	Legal Services	(304) 598-5408	Research & Development	(304) 285-6409
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