NDA 19-832 **June 5, 1998**

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
Executive Director, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Mr. Sisto:

Please refer to your new drug application dated February 18, 1988, and your resubmissions dated March 27, 1997 and April 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution.

We acknowledge receipt of your submissions dated:

November 19, 1997	March 10, 1998
December 18, 1997	April 3, 1998
January 22, 1998	April 17, 1998
February 6, 1998	May 1, 1998
February 12, 1998	May 13, 1998
February 25, 1998	

This new drug application has Orphan Drug designation and is indicated for use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to recommend approval under the Accelerated Approval Regulations (21 CFR 314 Subpart H) with the draft labeling in the submission dated February 6, 1998, and revised as agreed in the letter of February 25, 1998. Accordingly, the application is approved effective on the date of this letter.

As acknowledged in the approvable letter of November 26, 1997, and in your submission of March 10, 1998, you have agreed to comply with the conditions of the Accelerated Approval Regulations (21 CFR 314 Subpart H).

Additionally, we acknowledge receipt of your May 28, 1998 facsimile in which you agree to modify the May 13, 1998, protocol in accordance with the facsimile from the Division of Anti-Infective Drug Products dated May 28, 1998 (attached).

The final printed labeling (FPL) must be identical to the draft labeling submitted on February 6, 1998, and revised as agreed in the letter of February 25, 1998. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 19-832. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your commitments specified in your submissions dated January 22, 1998 and March 10, 1998. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

The Agency has granted 18 months of expiration dating for Sulfamylon finished product.

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 yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research