



NDA 20-677/S-006

Mylan Pharmaceuticals Inc.  
Attention: Andrea B. Miller, R.Ph., Esq.  
Executive Director, Regulatory Affairs  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, WV 26504-4310

Dear Ms. Miller:

Please refer to your supplemental new drug application dated March 6, 2003, received March 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zagam® (sparfloxacin) Tablets, 200 mg.

This changes being effected supplemental new drug application provides for the addition of hepatic failure, pancytopenia and torsades de pointes to the **ADVERSE REACTIONS** section, **Postmarketing Adverse Events** subsection of the Zagam® package insert.

We have completed the review of this supplemental application 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, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (text for the package insert submitted March 6, 2003).

Please submit the copies of final printed labeling (FPL) electronically 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, this submission should be designated "FPL for approved supplement NDA 20-677/S-006." Approval of this submission by FDA is not required before the labeling is used.

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

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.  
Director  
Division of Special Pathogen and Immunologic Drug  
Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

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/s/

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Renata Albrecht  
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