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APPLICATION NUMBER:

20-677/S-003

APPROVAL LETTER

DIVFILE # 20-677

NDA 20-677/S-003

DEC 10 1999

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

Dear Mr. Sisto:

Please refer to your supplemental new drug application dated July 7, 1999, received July 8, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zagam® (sparfloxacin) Tablets, 200 mg.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for alternate packaging site.

We have completed the review of this supplemental application and it is approved.

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, contact Laurie Bernato, R.N., M.S., Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

/S/

Norman R. Schmuff, Ph.D.
Chemistry Team Leader for the
Division of Special Pathogens and Immunologic Drug Products, (HFD-590)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research