CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-677/S-003

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

412

Divfile #20-677

SUPAC / PAC ROUTING FORM

This form is to accompany all SUPAC / PAC supplements. Upon completion return to Document Room with appropriate letter (if required) for letter issuance, data entry, and filing.

I. To be completed by Document Room using industry cover letter:

DATE PROCESSED: July 09, 1999

APPLICATION #: N-20677 SUPPLEMENT #: SCM-003

SUPAC modifier (amendment type code):
- ✓ SI - (SUPAC-IR) Immediate release solid oral dosage forms
- ___ SS - (SUPAC-SS) Semisolid topical dosage forms
- ___ SE - (SUPAC-MR) Modified release oral dosage forms
- ___ ST - (SUPAC-TDS) Transdermal dosage forms
- ___ SP - (PAC-SAS) Sterile Aqueous Solutions
- ___ SL - (PAC-ATLS) Analytical Testing Laboratory Sites

Type of change (event code): (check all that apply)
- ___ S1 - Batch Size (Scale-Up/Scale-Down)
- ___ S2 - Components and Composition
- ___ S3 - Manufacturing Equipment
- ___ S4 - Manufacturing Process
- ✓ S5 - Site (e.g. manufacturing, packaging, testing)

Supplement Type:
- ___ (PL) PRIOR APPROVAL *Skip to Item IV below*
- ✓ (CBE) CHANGES BEING EFFECTED *Proceed with Items II, III, & IV*

II. To be determined by Chemistry Division:

___ (IS) INCORRECT SUPPLEMENT CATEGORY (non-SUPAC)
Chemistry Division Team Leader: _____ Date: _____

___ (GR) QUALIFIES as CBE
Chemistry Division Team Leader: /S/ Date: 7/16/99

___ (DN) DOES NOT QUALIFY as CBE NOTE: SUPAC CBE Checklist: Failure to Qualify, or other qualification statement required

Chemistry Division Team Leader: _____ Date: _____

Chemistry Division Director concurrence: _____ Date: _____

~~**III. The (___ Project Manager ___ Chemistry Team Leader) will prepare notification of non qualification letter in**~~ accordance with ____ division policy on Chemistry, Manufacturing, and Control supplement letters.

IV. To Document Room:

Record SUPAC codes as special amendment for supplement.
File in archival submission.

cc: HFD-358, DAVE MORLEY
DIVISION FILE
PROJECT MANAGER
LENA STAUNTON CDRII

5/28/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

DivFile

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-677/S-003

JUL 20 1999

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

Dear Mr. Sisto:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Zagam® (sparfloxacin) 200mg Oral Tablets

NDA Number: 20-677

Supplement Number: S-003

Date of Supplement: July 7, 1999

Date of Receipt: July 8, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 6, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research