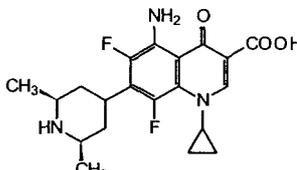


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-677/S-003

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW				1. ORGANIZATION: HFD-590		2. NDA NUMBER: 20-677	
3. NAME AND ADDRESS OF APPLICANT: (City and State) Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Road Morgantown, WV 2504-4310				4. AF NUMBER:			
				5. SUPPLEMENT(S):			
				NUMBER(S): SCM-003		DATE(S): July 8, 1999	
6. NAME OF DRUG: Zagam® Tablets				7. NONPROPRIETARY NAME: sparfloxacin			
8. SUPPLEMENT(S) PROVIDES FOR: Alternate packaging site.				9. AMENDMENTS/REPORTS:			
10. PHARMACOLOGICAL CATEGORY: Antibacterial		11. HOW DISPENSED: [X] Rx [] OTC		12. RELATED IND/NDA/DMF(S):			
13. DOSAGE FORM(S): Tablet			14. POTENCY(IES): 200 mg				
15. CHEMICAL NAME AND STRUCTURE: (cis)-5-Amino-1-cyclopropyl-7-(3,5-dimethyl-1-piperazinyl)-6,8-difluoro-1,4-dihydro-4-oxo-3-quinolonecarboxylic acid				16. MEMORANDA:			
							
17. COMMENTS: This CBE supplement provides for an additional site for blister packaging Zagam® tablets. The container/closure components are the same as those already approved. OC has rated the firm as acceptable.							
18. CONCLUSIONS AND RECOMMENDATIONS: The information submitted meets the requirements for a stand alone packaging site change outlined in the February 18, 1997 SUPAC QA Letter to NDA, ANDA and AADA Holders. This supplemental application is recommended for APPROVAL.							
19. REVIEWER: Gene W. Holbert, Ph.D.		SIGNATURE:			DATE COMPLETED:		
20. CONCURRENCE: Norman R. Schmuff, Ph.D.							
DISTRIBUTION:	X	Original NDA	X	HFD-590: NSchmuff	X	HFD-590:	
	X	Division File HFD-590	X	HFD-590: GHolbert	X	HFD-830: CChen	

REVIEW NOTES

The alternate packaging site will be:

[]

_____ has provided a _____ for their Type I DMF _____

_____ will use the currently approved container/closure system, which consists of:

[]

An EER was submitted on August 9, 1999, and the firm was given an acceptable rating based on profile. _____ has certified that it is in conformity with current Good Manufacturing Practices.

Mylan Pharmaceuticals has committed to placing the first production batch of Zagam packaged at _____ into the long-term stability monitoring program with the data to be submitted in the annual report.

APPEARS THIS WAY
ON ORIGINAL

17-AUG-1999

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Page 1 of 1

Application: NDA 20677/003	Priority: 1S	Org Code: 590
Startup: 08-JUL-1999 Regulatory Due: 08-NOV-1999	Action Goal:	District Goal: 04-OCT-1999
Applicant: MYLAN PHARMS 701 CHESTNUT RIDGE RD MORGANTOWN, WV 265044310	Brand Name: ZAGAM (SPARFLOXACIN) 200MG TABLETS	Established Name:
	Generic Name: SPARFLOXACIN	Dosage Form: TAB (TABLET)
	Strength: 200 MG	
FDA Contacts: D. BERNATO (HFD-590) 301-827-2387 , Project Manager		
G. HOLBERT (HFD-590) 301-827-2399 , Review Chemist		
N. SCHMUFF (HFD-590) 301-827-2425 , Team Leader		

Overall Recommendation:

ACCEPTABLE on 09-AUG-1999 by S. ADAMS (HFD-320) 301-594-0095

Establishment: []

DMF No: -
AADA No:

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 09-AUG-1999
Decision: ACCEPTABLE
Reasons: BASED ON PROFILE

Responsibilities: []

APPEARS THIS WAY
ON ORIGINAL