

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**20-677/S-001, S-002**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

NDA 20-677/S-001, S-002

**Regulatory Review Officer Review of Final Printed Labeling (FPL):**

**Materials Reviewed:**

Product	NDA #	FPL for SLR #	Letter Date	Receipt Date	Completed Date
Zagam <sup>®</sup> (sparfloxacin)Tablets, 200 mg	20-677	001, 002	August 11, 2000 (paper) November 14, 2000 (electronic)	August 14, 2000 (paper) November 15, 2000 (electronic)	September 13, 2002

- Approved draft labeling for NDA 20-677/S-001, S-002 dated October 19, 1999

**Sponsor:** Mylan Pharmaceuticals, Inc.

**Background:**

Supplement 001 was submitted in response to the Federal Register notice dated August 27, 1997 that advised companies to revise geriatric labeling.

Supplement 002 was submitted in response to two FDA letters to the company as follows:

1. FDA letter dated May 29, 1998 advising the company to incorporate class labeling revisions related to CNS toxicity and pediatric word changes.
2. FDA letter to the sponsor dated July 27, 1998 advising the company to incorporate class labeling revisions related to Videx<sup>®</sup> drug interaction.

Draft labeling for S-001 and S-002 was approved by the Division on October 19, 1999.

**Review and Comments:**

The approved draft labeling for the Zagam<sup>®</sup> package insert dated October 19, 1999 was electronically compared to the FPL submitted electronically on November 14, 2000. They were found to be identical.

**Recommendations:**

An Acknowledge and Retain letter should be issued for informing the applicant that the FPL for Zagam<sup>®</sup> is acceptable.

Robin Anderson, RN, MBA  
Regulatory Review Officer,  
HFD-590

**cc:**  
HFD-590/ActingDivDir/R. Albrecht  
HFD-590/PM/D. Willard

**Concurrence:**  
HFD-590/ActingDivDir/R. Albrecht 9/18/02

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/s/  
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Robin Anderson  
9/18/02 11:18:03 AM  
INTERDISCIPLINARY

Renata Albrecht concurred with this review on 9/18/02.

Renata Albrecht  
9/18/02 03:54:53 PM  
MEDICAL OFFICER

**APPEARS THIS WAY  
ON ORIGINAL**



Food and Drug Administration  
Rockville MD 20857

NDA 20-677/S-001

Mylan Pharmaceuticals Inc  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, West Virginia 26504- 4310

OCT 2 1998

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 ) Tablets 200 Mg

NDA Number: 20-677

Supplement Number: S-001

Date of Supplement: September 18, 1998

Date of Receipt: September 21, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on November 20, 1998 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 Pathogens 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

**APPEARS THIS WAY  
ON ORIGINAL**

Sincerely,

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



NDA 20-677/S-001, S-002

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:

We acknowledge receipt of your August 11, 2000 (paper) and November 14, 2000 (electronic) submissions containing final printed labeling in response to our October 19, 1999 letter approving your supplemental new drug applications for Zagam<sup>®</sup> (sparfloxacin) Tablets, 200 mg.

We have reviewed the labeling that you submitted in accordance with our October 19, 1999 letter and we find it acceptable.

If you have any questions, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

*{See appended electronic signature page}*

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

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this page is the manifestation of the electronic signature.**  
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/s/

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Renata Albrecht  
9/18/02 03:57:24 PM