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*APPLICATION NUMBER:*

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

**CLINICAL PHARMACOLOGY AND**  
**BIOPHARMACEUTICS REVIEW(S)**

DF

JAN 4 1999

**CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS REVIEW**

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**NDA:** 20-677; S-001, 002  
Zagam<sup>R</sup> (Sparfloxacin) tablets

**SUBMISSION DATE:** September 18, 1998  
November 25, 1998

Mylan Pharmaceuticals, Inc.  
781 Chestnut Ridge Road  
Morgan Town, WV 26504

**REVIEWER:** Funmilayo O. Ajayi, Ph.D.

**TYPE OF SUBMISSION:** Labeling Supplement

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**BACKGROUND:** The sponsor provides information in response to the Geriatric rule and a response to the Agency letters of May 29, 1998 and July 27, 1998. The supplement is for the Geriatric Use subsection of the product label. The Clinical Pharmacology section of the approved label has information on the Geriatrics.

**FINDINGS:** There are no changes to the Clinical Pharmacology section of the label. The sponsor also provides a modified version of their product label based on the requested changes outlined in the Agency letters of May 29, 1998 and July 27, 1998.

**RECOMMENDATION:** The submitted information has been reviewed and found acceptable.

*IS/* 1/4/99  
Funmilayo O. Ajayi, Ph.D  
Div. of Pharmaceutical Evaluation III

*IS/* 1/4/99  
FT initialed by Frank Pelsor, PharmD.....

cc: NDA 20-677; HFD-590 (Clinical Division)  
HFD-880 (DPE3, Pelsor, Ajayi)  
CDR (Attn: B. Murphy)