

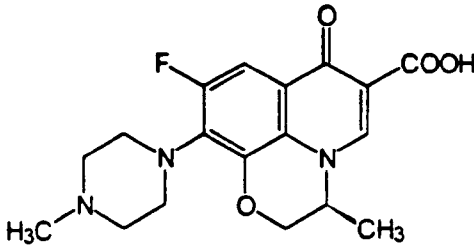

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-634/S-008, S-009

20-635/S-007, S-008

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW				1. ORGANIZATION HFD-590		2. NDA NUMBER 20-635	
3. NAME AND ADDRESS OF APPLICANT (City and State) The R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869-0602				4. AF NUMBER			
				5. SUPPLEMENT(S):			
				NUMBER(S)		DATE(S)	
SE1-007		March 31, 1999					
6. NAME OF DRUG Levaquin® Tablets				7. NONPROPRIETARY NAME Levofloxacin			
8. SUPPLEMENT(S) PROVIDES FOR: New indication: penicillin- <u> </u> -resistant strains of <i>S. pneumoniae</i>				9. AMENDMENTS/REPORTS			
10. PHARMACOLOGICAL CATEGORY Antibacterial		11. HOW DISPENSED [X] Rx [] OTC		12. RELATED IND/NDA/DMF(S) IND 36,627, 38,368 NDA 20-634			
13. DOSAGE FORM(S) Injection				14. POTENCY(IES) 25 mg/mL, 5 mg/mL			
15. CHEMICAL NAME AND STRUCTURE S-(-)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid hemihydrate				16. MEMORANDA			
							
17. COMMENTS: This supplement supports a revision to the sponsor's approved community-acquired pneumonia claim due to <i>S. pneumoniae</i> to specifically indicate that Levaquin is effective in treating penicillin- <u> </u> -resistant strains of <i>S. pneumoniae</i> . There are no changes to the Description, Preparation for Administration or How Supplied sections of the package insert. A claim of categorical exclusion from Environmental Assessment under 21 CFR 25.31(b) is contained in the cover letter. There is no information to indicate that additional environmental information is required.							
18. CONCLUSIONS AND RECOMMENDATIONS: From a CMC viewpoint, this supplement may be approved.							
19. REVIEWER:							
NAME		SIGNATURE			DATE COMPLETED		
Gene W. Holbert, Ph.D.					9-29/1999		
CONCURRENCE:					9/29/99		
Norman R. Schuff, Ph.D.							
DISTRIBUTION:	X	Original: NDA 20-635	X	HFD-590: NSchuff	X	HFD-590: RAnderson	
	X	Division File: HFD-590	X	HFD-590: GHolbert	X	HFD-830: CChen	

Fr. + 5/2
R. ANDERSON

SUPPLEMENTAL NDA CHEMIST'S REVIEW			1. ORGANIZATION HFD-590		2. NDA NUMBER 20-634	
NAME AND ADDRESS OF APPLICANT (City and State) The R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869-0602				4. AF NUMBER		
				5. SUPPLEMENT(S):		
				NUMBER(S) SE1-008		DATE(S) March 31, 1999
6. NAME OF DRUG Levaquin® Tablets			7. NONPROPRIETARY NAME Levofloxacin			
8. SUPPLEMENT(S) PROVIDES FOR: New indication: penicillin-resistant strains of <i>S. pneumoniae</i>				9. AMENDMENTS/REPORTS		
10. PHARMACOLOGICAL CATEGORY Antibacterial		11. HOW DISPENSED [X] Rx [] OTC		12. RELATED IND/NDA/DMF(S) IND 36,627, 38,368 NDA 20-635		
13. DOSAGE FORM(S) Tablets			14. POTENCY(IES) 250 and 500 mg			
15. CHEMICAL NAME AND STRUCTURE <i>S</i> -(-)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7 <i>H</i> -pyrido[1,2,3- <i>de</i>][1,4]benzoxazine-6-carboxylic acid hemihydrate				16. MEMORANDA		
17. COMMENTS: This supplement supports a revision to the sponsor's approved community-acquired pneumonia claim due to <i>S. pneumoniae</i> to specifically indicate that Levaquin is effective in treating penicillin-resistant strains of <i>S. pneumoniae</i> . There are no changes to the Description or How Supplied sections of the package insert. A claim of categorical exclusion from Environmental Assessment under 21 CFR 25.31(b) is contained in the cover letter. There is no information to indicate that additional environmental information is required.						
18. CONCLUSIONS AND RECOMMENDATIONS: From a CMC viewpoint, this supplement may be approved.						
19. REVIEWER:						
NAME Gene W. Holbert, Ph.D.		SIGNATURE 		DATE COMPLETED Sep 23, 1999		
20. CONCURRENCE:						
Norman R. Schmuff, Ph.D.						
DISTRIBUTION:	<input checked="" type="checkbox"/>	Original: NDA 20-634	<input checked="" type="checkbox"/>	HFD-590: NSchmuff	<input checked="" type="checkbox"/>	HFD-590: RAnderson
	<input checked="" type="checkbox"/>	Division File: HFD-590	<input checked="" type="checkbox"/>	HFD-590: GHolbert	<input checked="" type="checkbox"/>	HFD-830: CChen