CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-404

21-405

21-061/s010, s016

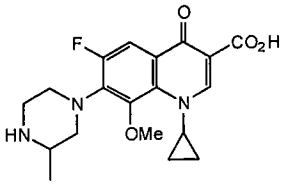
21-062/s011, s017

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION: HFD-590	2. NDA NUMBER: 21-062
3. NAME AND ADDRESS OF APPLICANT: *(City and State)* Bristol-Myers Squibb Co. 5 Research Parkway Wallingford, CT 06492	4. SUBMISSION TYPE: CBE 5. SUPPLEMENT(S): NUMBER(S): SLR-017 / DATE(S): 10-MAY-2002	
6. NAME OF DRUG: TEQUIN Injection	7. NONPROPRIETARY NAME: gatifloxacin	
8. SUPPLEMENT PROVIDES FOR: Changing the established name of the product to TEQUIN® (gatifloxacin in 5% dextrose) Injection for the ready to use formulation.	9. AMENDMENTS/REPORTS:	
10. PHARMACOLOGICAL CATEGORY: Antibacterial (synthetic)	11. HOW DISPENSED: [X] Rx [ ]OTC	12. RELATED IND/NDA/DMF(S): IND 52,081 and 53,521 NDA 21-061
13. DOSAGE FORM(S): Intravenous solution	14. POTENCY(IES): 200 and 400 mg	

15. CHEMICAL NAME AND STRUCTURE:

(±)-1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(3-methyl-1-piperaziny)-4-oxo-3-quinolinecarboxylic acid sesquihydrate



16. MEMORANDA:

17. COMMENTS: This supplement provides for changing the name of the ready-for-use product from TEQUIN® (gatifloxacin) Injection to TEQUIN® (gatifloxacin in 5% dextrose) Injection in order to highlight hypoglycemic and hypoglycemic events that have been reported in patients treated with TEQUIN®. Revisions to the package insert will be made immediately, and all product shipped after June 30, 2002 will contain the revised insert. Revisions to artwork for the primary bag and overwrap for the gatifloxacin in 5% dextrose minibags will be made at the next printing, however, all product shipped after June 30 will bear a sticker indicating the name change. It should be noted that the "How Supplied" section of the Package Insert does not reflect the replacement of the 7-tablet Teq-Paq with the recently approved 5-tablet Teq-Paq.

18. CONCLUSIONS AND RECOMMENDATIONS: The sponsor should be reminded to change the "How Supplied" section to reflect the new 5-tablet Teq-Paq. APPROVAL of this supplement is recommended.

19. REVIEWER:	SIGNATURE:	DATE COMPLETED:
Gene W. Holbert, Ph.D.		15-JUL-2002
20. CONCURRENCE: Norman R. Schmuff, Ph.D.		

DISTRIBUTION:	X	Original: NDA 21-062	X	HFD-590: N. Schmuff	X	HFD-590: D. Willard
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/s/

Gene Holbert
7/18/02 04:40:49 PM
CHEMIST

Norman Schmuff
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CHEMIST