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APPLICATION NUMBER:
NDA 20-958 / S-002

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division HFD-560	2. NDA Number 20-958
3. Name and Address of Applicant Merck & Co. Inc. Sumneytown Pike P.O. Box 4, BLA-33 West Point, PA 19486	4. Supplement Number: SCF 002 Letter Date: 7/5/01 Stamp Date: 7/6/01 Due Date : 11/06/01	
5. Name of Drug Pepcid™ Complete	6. Nonproprietary Name Famotidine, Calcium Carbonate and Magnesium Hydroxide Tablets	
7. Supplement Provides for: A new berry flavored product, which includes a new method of analysis of famotidine in the drug product		8. Amendment(s) Various – see next page for list
9. Pharmacological Category Prevention of heartburn and as an antacid.	10. How Dispensed OTC	11. Related Documents DMF —
12. Dosage Form Tablets	13. Potency(ies) 10 mg famotidine, 800 mg calcium carbonate and 165 mg magnesium hydroxide /tablet	
14. Chemical Names and Structures See USAN		
15. Comments This is a PA supplement. The DMFs of the flavor was found to be adequate. Details of the review of the supplement are in the attached notes. The company has asked for and can be granted an expiration period of 36 months (same as for the mint flavored tablets). A MV package is submitted. The methods for famotidine and its degradates will need to be validated by the FDA labs.		
16. Conclusions and Recommendations The applicant has submitted most of the information requested satisfactorily. It is recommended that the supplement be approved.		
17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist	Signature	Date
Concurrence John Smith, Ph.D. Chemistry Team Leader		

APPROVE

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/s/

Vispi Bhavnagri
11/2/01 09:41:22 AM
CHEMIST

John Smith
11/5/01 12:41:56 PM
CHEMIST