

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-325 / S-015

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division HFD-560	2. NDA Number 20-325
3. Name and Address of Applicant Merck and Co., Inc. Contact: Ms Brenda A. McGuire, M.S., R.N. Associate Director, OTC Regulatory Affairs Sumneytown Pike, P.O. Box 4, BLX - 29 West Point, PA 19486	4. Supplement Number: SE2-015 Letter Date: 11/22/02 Stamp Date: 11/22/02 Due Date : 8/22/03	
5. Name of Drug Pepcid TM Film Coated Tablets	6. Nonproprietary Name Famotidine Tablets, USP	
7. Supplement Provides for: Supporting the 20 mg strength for OTC use, which includes manufacturing the drug product at Merck and Co. (West Point, PA), labeling and packaging the drug product by _____, and packaging the drug product in various container closure systems (HDPE bottles, child resistant and non-child resistant blisters and pouches)		8. Amendment(s) BC dated 12/13/03 BC Dated 3/7/03 BC Dated 8/4/03
9. Pharmacological Category Antacid	10. How Dispensed OTC	11. Related Documents
12. Dosage Form Tablets	13. Potency(ies) 20 mg	
14. Chemical Name and Structure See USAN		
15. Comments This is an efficacy (SE-2) supplement. The EER was found to be acceptable. The company has asked for and been granted a categorical exclusion from preparing an EA. The CC systems have previously been approved for the 20 mg prescription strength or the 10 mg OTC strength tablets. The company had submitted all the recommended information for the manufacturing facilities and packaging the drug product in various container closure systems (see attached reviewer's notes).		
16. Conclusions and Recommendations Recommend approval from the CMC standpoint.		
17. Reviewing Chemist Vispi P. Bhavnagri, Ph.D.		
18. Team Leader John Smith, Ph.D.		

APPROVAL

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/s/

Vispi Bhavnagri
8/8/03 01:28:10 PM
CHEMIST

John Smith
8/8/03 01:38:39 PM
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