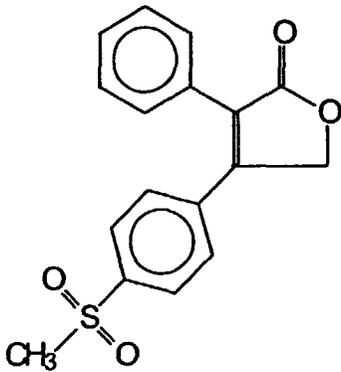


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-042/S-007, S-008, S-010, S-012, S-013, S-014 and 21-052/S-004, S-005, S-006, S-007, S-008, S-009

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division, HFD-550	2. NDA Number: 21-042	
3. Name and Address of Applicant Merck & Co. Inc., Sumneytown Pike, P O. Box 4, BLA-20, West Point PA 19486	4. Supplement Number: SE1-012		
	Letter Date 2-28-01	Stamp Date 3-2-01	Review Date 4-6-01
5. Name of Drug:: Vioxx	6. Nonproprietary Name: Rofecoxib		
7. Supplement Provides for: To provide labeling revision for the following sections namely, "Clinical Studies", "Indications and Usage", "Adverse Reactions", and "Dosage and Administration" to support a Rheumatoid Arthritis Indication.		8. Amendment(s): 3-23-01	
9. Pharmacological Category, NSAID	10. How Dispensed, Rx	11. Related Documents, NA	
12. Dosage Form: Tablets	13. Potency(ies), 12.5, 25 & 50 mg		
14. Chemical Name and Structure:			
 <p>formula: C₁₇H₁₄O₄S m. w. : 314.36</p>			
15. Supporting Document: NA			
16. Comments: There are no changes in the CMC sections of the labeling (Description and How Supplied). Firm states that the supplement meets the requirements of a categorical exclusion under 21 CFR §25.31(b) because the estimated concentration of the substance at the point of entry into the environment will be below 1 ppb (Amendment of 3/23/01). There are no other CMC issues that required a chemistry review.			
17. Conclusions and Recommendations: Approvable pending on the medical officer's review of the submission.			
18. Name:	Signature:	Date	
Review Chemist	Bart Ho	April 13, 2001	
Acting Team Leader:	Charlotte Yaciw		

cc: NDA 21-042
HFD-550/Division File
HFD-550/B. Ho
HFD-550/Yaciw
HFD-550/Cook
HFD-830/Chen

Doc ID: 21042SE1012.DOC

/s/

Bartholomew Ho
4/13/01 02:09:01 PM
CHEMIST

Charlotte Yaciw
4/16/01 09:57:43 AM
CHEMIST
Concur.

**APPEARS THIS WAY
ON ORIGINAL**