CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-042 / S-011

Trade Name: Vioxx

Generic Name: Rofecoxib

Sponsor: Merck & Co

Approval Date: April 13, 2001

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APPLICATION NUMBER:

21-042 / S-011

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-042/S-011

Merck Research Laboratories
Attention: Robert E. Silverman, M.D., Ph.D.
Senior Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, Pennsylvania 19486

Dear Dr. Silverman:

Please refer to your supplemental new drug application dated February 16, 2001, received February 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx (rofecoxib tablets) Tablets, 12.5 mg, 25 mg, and 50 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sandra N. Folkendt, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

John Smith, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, (HFD-550)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Smith
6/13/01 02:34:29 PM

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: SCS-011	
	Letter Date 2-16-01	**Stamp Date** 2-21-01	**Due Date** 8-20-01, primary
5. Name of Drug:: Vioxx	6. Nonproprietary Name: Rofecoxib	
7. Supplement Provides for: Merck's analytical testing laboratory located at Merck & Co., Inc., 4633 Merck Road, Wilson, North Carolina 27893		8. Amendment(s): None
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: See USAN		
15. Supporting Document: NA		
16. Comments: The [redacted] has been inspected by the compliance and was found acceptable. A copy of the EER is attached at the end of this review. The test method approved in the application and methods that have been implemented under 21 CFR 314.70(d) are used. All post approval commitments made by the applicant related to the test methods have been fulfilled. The approved tests and acceptance criteria which are currently used and will continue to be used to analyze the [redacted] Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR §25.31(a). The supplement meets the requirements of a categorical exclusion under 21 CFR §25.31(a) because it will not increase the use of the drug. To the best of the firm's knowledge no extraordinary circumstances exist in regards to this action.		
17. Conclusions and Recommendations: Recommend Approve.		
18. Name:	Signature:	Date
Review Chemist	Bart Ho	04/16/01
Acting Team Leader:	Charlotte Yaciw	

Doc ID: 21042SCSI1AP.DOC

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APPLICATION NUMBER:

21-042 / S-011

CHEMISTRY REVIEW(S)

30-MAR-2001 FDA CDER EES Page 1 of 1

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 21042/011** Priority: **1P** Org Code: **550**
Stamp: **20-FEB-2001** Regulatory Due: **20-AUG-2001** District Goal: **16-JUL-2001**

Applicant: **MERCK RES** Brand Name: **VIOXX (ROFECOXIB) 12.5/25MG Tablets**
SUMNEYTOWN PIKE BLA-20
WEST POINT, PA 194860004

Established Name:
Generic Name: **ROFECOXIB**
Dosage Form: **TAB (TABLET)**
Strength: **12.5 & 25 MG**

FDA Contacts:			
	S. FOLKENDT	**(HFD-550)**	**301-827-2090 , Project Manager**
	B. HO	**(HFD-550)**	**301-827-2050 , Review Chemist**
	C. YACIW	**(HFD-830)**	**301-827-2296 , Team Leader**

Overall Recommendation:
ACCEPTABLE on 26-MAR-2001by J. D AMBROGIO(HFD-324)301-827-0062

Establishment: [redacted]

DMF No:
AADA No:

Profile: **CTL** CAI Status: NONE Responsibilities: [redacted]
STABILITY
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-MAR-2001**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

/s/

Bartholomew Ho
4/16/01 01:50:49 PM
CHEMIST

Charlotte Yaciw
4/16/01 02:00:14 PM
CHEMIST
Concur. Ready for letter to be written..