CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-042 / S-015

Trade Name: Vioxx

Generic Name: Rofecoxib

Sponsor: Merck & Co

Approval Date: April 6, 2002

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APPLICATION NUMBER:

21-042 / S-015

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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-015

Merck and Co., Inc.
Attention: Robert E. Silverman, M.D., Ph.D.
Senior Director, Regulatory Affairs
c/o Merck Research Laboratories (BLA-20)
Sumneytown Pike, P.O. Box 4
West Point, PA 19486

Dear Dr. Silverman:

Please refer to your supplemental new drug applications dated December 07, 2001, received December 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx™ (rofecoxib tablets) 12.5 mg, 25 mg, 50 mg.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for Merck's _____ facility as an alternate source for Vioxx, 50 mg.

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 Barbara Gould, 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

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/s/

John Smith
6/6/02 03:07:11 PM

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APPLICATION NUMBER:

21-042 / S-015

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: SCM-015 **Letter Date** 12-7-01 / **Stamp Date** 12-10-01 / **Due Date** 6-10-02, primary	
5. Name of Drug:: Vioxx	6. Nonproprietary Name: Rofecoxib	
7. Supplement Provides for: [redacted] xx, 50 mg for the US market.		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:

[redacted] has been inspected by the compliance and was found acceptable. A copy of the EER is attached at the end of this review. There is only one minor change in the methods of manufacture. The change should not have any impact on the quality of the drug product. Quality control of the drug product remains the same. Batches sizes manufactured at the [redacted] whereas at the currently approved manufacturing site at [redacted] The difference in batch sizes is within SUPAC guide requirement. The approved tests and acceptance criteria which are currently used will continue to be used to analyze the drug product in this [redacted]

Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR §25.31(x). The supplement meets the requirements of a categorical exclusion under 21 CFR §25.31(x) because it will not increase the use of the drug.

17. Conclusions and Recommendations: Recommend Approve.

18. Name:	Signature:	Date
Review Chemist	Bart Ho	04/29/02
Team Leader:	John Smith	

Doc ID: 21042SCM15NEWSITE.DOC

7 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1.9

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/s/

Bartholomew Ho
4/29/02 10:09:12 AM
CHEMIST

John Smith
4/29/02 10:24:22 AM
CHEMIST