CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-042 / S-016
21-052 / S-010

Trade Name: Vioxx

Generic Name: Rofecoxib

Sponsor: Merck & Co

Approval Date: June 25, 2002

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APPLICATION NUMBER:

21-042 / S-016
21-052 / S-010

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APPLICATION NUMBER:

21-042 / S-016

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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-016
NDA 21-052/S-010

Merck & Co., Inc.
Attention: Ned S. Braunstein, M.D.
Director, Regulatory Affairs
PO Box 2000, RY33-720
Rahway, NJ 07065-0900

Dear Dr. Braunstein:

Please refer to your supplemental new drug applications dated January 15, 2002, received January 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx (rofecoxib) tablet, 12.5 mg/25 mg/50mg (NDA 21-042) and oral suspension, 12.5 mg/5 ml, 25 mg/5/ml (NDA 21-052).

These supplemental new drug applications provide the addition of Merck's [redacted] or the manufacture of rofecoxib active drug substance for U.S. market.

We have completed the review of these supplemental applications, and they are 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 Jane A. Dean, RN, MSN, Regulatory Health 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
6/25/02 03:17:52 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-042 / S-016

21-052 / S-010

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division, HFD-550	2. NDA 21-042 & 21-052	
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-016 (21-042) SCM-010 (21-052)		
	Letter Date 1-14-02	**Stamp Date** 1-15-02	**Due Date** 5-15-02, primary
5. Name of Drug:: Vioxx	6. Nonproprietary Name: Rofecoxib		
7. Supplement Provides for: To add [redacted] for manufacture of rofecoxib active drug substance for the US market.		8. Amendment(s): None	
9. Pharmacological Category, NSAID	10. How Dispensed, Rx	11. Related Documents, NA	
12. Dosage Form: Tablets (21-042) Suspension (21-052)	13. Potency(ies), 12.5, 25 & 50 mg (21-042) 12.5 mg and 25 mg per 5 mL (21-052)		
14. Chemical Name and Structure: See USAN			

15. Supporting Document: NA

16. Comments:

There are no changes in the methods of manufacture of the drug substance. The only difference is the batch size, [redacted]. The approved tests and acceptance criteria, which are currently used in [redacted] will continue to be used in this [redacted] facility. Test results for batches manufactured at the two sites are comparable.

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.

The Merck's facility at [redacted] has been inspected by the compliance and was found acceptable. A copy of the EER is attached at the end of this review.

17. Conclusions and Recommendations: Recommend Approve

18. Name:	Signature:	Date
Review Chemist	Bart Ho	06/28/02
Team Leader:	John Smith	

Doc ID: 21042SCM16NEWSITE.DOC

3 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1a

12-FEB-2002 FDA CDER EES Page 1 of 1

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 21042/016** Priority: **1P** Org Code: **550**
Stamp: **15-JAN-2002** Regulatory Due: **15-MAY-2002** Action Goal:
District Goal: 10-**APR-2002**
Brand Name: **VIOXX (ROFECOXIB) 12.5/25MG TABLETS**
Applicant: **MERCK RES**
SUMNEYTOWN PIKE BLA 20
WEST POINT, PA 194860004

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

FDA Contacts:				
	B. GOULD	**(HFD-550)**	**301-827-2090**	**, Project Manager**
	B. HO	**(HFD-550)**	**301-827-2050**	**, Review Chemist**
	J. SMITH	**(HFD-550)**	**301-827-2529**	**, Team Leader**

Overall Recommendation:
ACCEPTABLE on 13-JUN-2002 by S. ADAMS (HFD-324)301-594-0095

Establishment

DMF No:)A No:
Profile: **CSN** OAI Status: **NONE** Responsibil
Responsibilities:
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **13-JUN-2002**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

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/s/

Bartholomew Ho
6/28/02 01:18:36 PM
CHEMIST

John Smith
6/28/02 01:41:11 PM
CHEMIST
Approval letter was signed on 6/25/02.

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APPLICATION NUMBER:

21-042 / S-016

21-052 / S-010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-042/S-016
NDA 21-052/S-010

PRIOR APPROVAL SUPPLEMENT

Merck & Co., Inc.
Attention: Robert E. Silverman, M.D., Ph.D.
Senior Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Silverman:

We have received your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
21-042	S-016	VioxxTM (rofecoxib) Tablets 12.5 mg, 25 mg, 50 mg
21-052	S-010	VioxxTM (rofecoxib) Tablets 12.5 mg/5 mL, 25 mg/5 mL

Date of Supplements: January 14, 2002

Date of Receipt: January 15, 2002

These supplements propose the addition of a [redacted] ce of rofecoxib.

Unless we notify you within 60 days of our receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the Act on March 15, 2002 in accordance with 21 CFR 314.101(a). If the applications are filed, the primary user fee goal date will be May 15, 2002 and the secondary user fee goal date will be July 15, 2002.

Please cite the application numbers listed above at the top of the first page of any communications concerning these applications. All communications concerning these supplemental applications should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Attention: Division Document Room
HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Attention: Division Document Room
HFD-550
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Barbara Gould, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Barbara Gould
2/28/02 05:28:41 PM
for Carmen DeBellas