

**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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**APPROVAL LETTER**



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 \_\_\_\_\_  
\_\_\_\_\_ 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/

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John Smith

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*APPLICATION NUMBER:*

**21-042 / S-016**

**21-052 / S-010**

**CHEMISTRY REVIEW(S)**

<b>Chemistry Review #1</b>	<b>1. Division, HFD-550</b>	<b>2. NDA 21-042 &amp; 21-052</b>	
<b>3. Name and Address of Applicant</b> Merck & Co. Inc., Sumneytown Pike, P O. Box 4, BLA-20, West Point PA 19486	<b>4. Supplement Number: SCM-016 (21-042)</b> SCM-010 (21-052)		
	<b>Letter Date</b> 1-14-02	<b>Stamp Date</b> 1-15-02	<b>Due Date</b> 5-15-02, primary
<b>5. Name of Drug:: Vioxx</b>	<b>6. Nonproprietary Name: Rofecoxib</b>		
<b>7. Supplement Provides for:</b> To add _____ for manufacture of rofecoxib active drug substance for the US market.		<b>8. Amendment(s):</b> None	
<b>9. Pharmacological Category, NSAID</b>	<b>10. How Dispensed, Rx</b>	<b>11. Related Documents, NA</b>	
<b>12. Dosage Form:</b> Tablets (21-042) Suspension (21-052)	<b>13. Potency(ies),</b> 12.5, 25 & 50 mg (21-042) 12.5 mg and 25 mg per 5 mL (21-052)		
<b>14. Chemical Name and Structure:</b> See USAN			
<b>15. Supporting Document:</b> NA			
<b>16. Comments:</b> There are no changes in the methods of manufacture of the drug substance. The only difference is the batch size, _____ The approved tests and acceptance criteria, which are currently used in _____ will continue to be used in this _____ 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 _____ has been inspected by the compliance and was found acceptable. A copy of the EER is attached at the end of this review.			
<b>17. Conclusions and Recommendations:</b> Recommend Approve			
<b>18. Name:</b>	<b>Signature:</b>	<b>Date</b>	
Review Chemist	Bart Ho	06/28/02	
Team Leader:	John Smith		

3 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry-1a

12-FEB-2002

FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

Page 1 of 1

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:  
Profile: **CSN** OAI Status: **NONE**  
Responsibilities:   
Last Milestone: **OC RECOMMENDATION**  
Milestone Date: **13-JUN-2002**  
Decision: **ACCEPTABLE**  
Reason: **DISTRICT RECOMMENDATION**

DA No:  
Responsibil 

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/s/

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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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**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**



NDA 21-042/S-016

NDA 21-052/S-010

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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/

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