

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**21-042 / S-004**

***Trade Name:*** Vioxx

***Generic Name:*** Rofecoxib

***Sponsor:*** Merck & Co

***Approval Date:*** March 7, 2000

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-042 / S-004**

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**APPROVAL LETTER**

NDA 21-042/S-004

MAR 7 2000

Merck Research Laboratories  
Attention: Eric A. Floyd, Ph.D.  
Associate Director, Regulatory Affairs  
Sumneytown Pike  
P.O. Box 4, BLA-20  
West Point, Pennsylvania 19486

Dear Dr. Floyd:

Please refer to your supplemental new drug application dated October 6, 1999, received October 7, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx (rofecoxib tablets) Tablets, 12.5 mg and 25 mg.

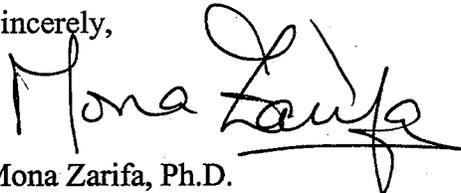
This supplemental new drug application provides for revisions to the dissolution specification for the 12.5 mg and 25 mg tablets.

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. Cook, Project Manager, at (301) 827-2090.

Sincerely,

A handwritten signature in black ink that reads "Mona Zarifa". The signature is written in a cursive style with a horizontal line underneath the name.

Mona Zarifa, Ph.D.

Acting Chemistry Team Leader, DNDC III 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

cc:

Archival NDA 21-042/S-004

HFD-550/Div. Files

HFD-550/S.Cook

HFD-550/Ho/Zarifa

HFD-095/DDMS-IMT

HFD-830/DNDC Division Director

DISTRICT OFFICE

Drafted by: SNC/March 3, 2000

Initialed by: *h Yaccov* 3-3-00

final:

filename:

**APPROVAL (AP)**

405 3021

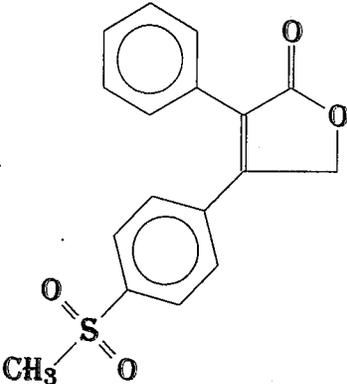
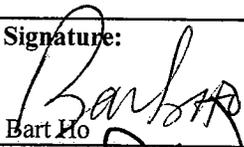
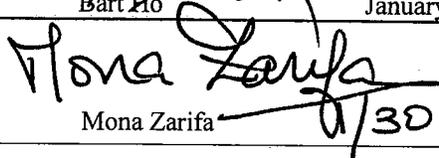
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*APPLICATION NUMBER:*

**21-042 / S-004**

**CHEMISTRY REVIEW(S)**

JAN 30 2000

<b>Chemistry Review #1</b>	<b>1. Division, HFD-550</b>	<b>2. NDA Number: 21-042</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: SCS-004</b>		
	<b>Letter Date</b> 10-6-99	<b>Stamp Date</b> 10-7-99	<b>Due Date</b> 2-7-00
<b>5. Name of Drug:: Vioxx</b>	<b>6. Nonproprietary Name: Rofecoxib</b>		
<b>7. Supplement Provides for:</b> revision to dissolution specification for 12.5 mg and 25 mg tablets		<b>8. Amendment(s):</b> NA	
<b>9. Pharmacological Category, NSAID</b>	<b>10. How Dispensed, Rx</b>	<b>11. Related Documents, NA</b>	
<b>12. Dosage Form: Tablets</b>	<b>13. Potency(ies), 12.5, 25 &amp; 50 mg</b>		
<b>14. Chemical Name and Structure:</b>			
		<b>FORMULA: C<sub>17</sub>H<sub>14</sub>O<sub>4</sub>S</b> <b>M. W. : 314.36</b>	
<b>15. Supporting Document: NA</b>			
<b>16. Comments:</b>			
<p>Merck requests to revise the dissolution specifications from Q = — 20 minutes to Q = — a 20 minutes for both 12.5 mg and 25 mg tablets. The dissolution is determined using the same apparatus — as in original NDA. Note that in a previous supplement (S-001), dated July 15, 1999, Merck had proposed a different —</p> <p style="text-align: right;">See review 21-042/S-001 for details.</p>			
<b>17. Conclusions and Recommendations: Recommend Approve.</b>			
<b>18. Name:</b>	<b>Signature:</b>	<b>Date</b>	
Review Chemist	 Bart Ho	January 28, 2000	
Acting Team Leader:	 Mona Zarifa	1/30/00	

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

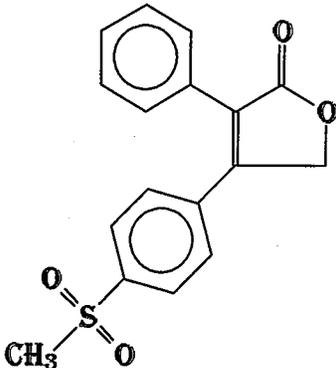
Doc ID: 21042S04R1.DOC

5 Page(s) Withheld

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Draft Labeling

Deliberative Process

<b>Chemistry Review #2</b>	<b>1. Division, HFD-550</b>	<b>2. NDA Number: 21-042</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: SCS-002</b>		
	<b>Letter Date</b> 5-26-99	<b>Stamp Date</b> 5-27-99	<b>Due Date</b> 9-27-99
<b>5. Name of Drug:: Vioxx</b>	<b>6. Nonproprietary Name: Rofecoxib</b>		
<b>7. Supplement Provides for:</b> A new dosage regimen of 50 mg and revision to dissolution specification for 12.5 mg and 25 mg tablets		<b>8. Amendment(s):</b> 2/3/00, 2/11/00 and 2/18/00	
<b>9. Pharmacological Category, NSAID</b>	<b>10. How Dispensed, Rx</b>	<b>11. Related Documents, NA</b>	
<b>12. Dosage Form: Tablets</b>	<b>13. Potency(ies), 12.5, 25 &amp; 50 mg</b>		
<b>14. Chemical Name and Structure:</b>			
 <p><b>FORMULA: C<sub>17</sub>H<sub>14</sub>O<sub>4</sub>S</b> <b>M. W. : 314.36</b></p>			
<b>15. Supporting Document: NA</b>			
<b>16. Comments:</b> Merck requests to revise the dissolution specifications from Q = <del>10</del> 20 minutes to Q = <del>10</del> 20 minutes for both 12.5 mg and 25 mg tablets. The dissolution is determined using the same apparatus <del>as</del> in original NDA. Note that in a previous supplement (S-001), dated July 15, 1999, Merck had proposed a <del>revision</del> of Vioxx tablets. See review 21-042/S-001 for details.			
<b>17. Conclusions and Recommendations: Recommend Approve.</b>			
<b>18. Name:</b>	<b>Signature:</b>	<b>Date</b>	
Review Chemist	Bart Ho	April 24, 2000	
<b>Acting Team Leader:</b>	Mona Zarifa		

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

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