CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-042 /S-020, 021, 022
21-052 /S-014, 015, 016

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products

REGULATORY PROJECT MANAGER REVIEW

Application Numbers: NDA 21-042/S-020, 021, 022
NDA 21-052/S-014, 015, 016

Name of Drugs: Vioxx™ (rofecoxib tablets) 12.5 mg, 25 mg, and 50mg
Vioxx™ (rofecoxib suspension) 12.5 mg/5 mL, 25 mg/5 mL

Applicant: Merck & Co., Inc.
Attention: Ned Braunstein
P.O. Box 2000
RY 33-720
Rahway, NJ 07065

Material Reviewed:

Submission Dates: December 11, 2002, May 05, 2003, and June 17, 2003

Receipt Dates: December 12, 2002, May 07, 2003, and June 19, 2003

Background and Summary

Supplement 020 and 014 provide for changes to the Patient Product Information (PPI) to add colitis, and menstrual disorder to the Side Effect section for consistency with the current package circular.

Supplement 021 and 015 provide for changes to the Patient Product Information (PPI) to add ringing in the ears to the Side Effect section for consistency with the current package circular.

Supplement 022 and 016 provide for changes to the Package Circular to add post-marketing adverse experiences of aplastic anemia, pancytopenia, and epilepsy aggravated based on WAES reports. The Patient Product Information has been revised for consistency with the current package circular.

Review

The material used for the review of changes to the PPI consisted of the current labeling and the proposed labeling text for the PPIs. The material used in the review of the additional post-marketing adverse experiences to be added to the current label consistent of WAES reports.

The current package insert was compared to the proposed labeling text for the PPI and all additions to the PPI are consistent with the current package insert. The side effects added are all

expressed in layman terms.

The WAES reports were reviewed and the additional post-marketing adverse events were found to be acceptable.

Conclusions

All supplements reviewed above were found to be acceptable. An approval letter should be issued to the Sponsor.

Barbara Gould
Regulatory Health Project Manager

Comment/Concurrence:

Lourdes Villalba, M.D.
Medical Officer

Drafted: DRAFTER'S INITIALS/DATE
Revised/Initialed:
Finalized:
Filename: Document1

CSO LABELING REVIEW

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/s/

Barbara Gould
6/20/03 05:13:33 PM
CSO

Maria Villalba
6/24/03 03:10:12 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-020, 021, 022
NDA 21-052/S-014, 015, 016

CBE SUPPLEMENTS

Merck & Co., Inc.
Attention: Ned Braunstein
Senior Director, Regulatory Affairs
P.O. Box 2000
RY 33-720
Rahway, NJ 07065

Dear Dr Braunstein:

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

NDA Number	Supplement Numbers	Drug Name
21-042	020, 021, 022	Vioxx™ (rofecoxib tablets) 12.5 mg, 25 mg, and 50mg
21-052	014, 015, 016	Vioxx™ (rofecoxib suspension) 12.5 mg/5 mL, 25 mg/5 mL

Date of supplement: December 11, 2002, May 05, 2003, and June 17, 2003

Date of receipt: December 12, 2002, May 07, 2003, and June 19, 2003

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Supplement 022 and 016 provide for changes to the Package Circular to add post-marketing adverse experiences of aplastic anemia, pancytopenia, and epilepsy aggravated based on WAES reports. The Patient Product Information has been revised for consistency with the current package circular.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research

DIVISION of ANTI-INFLAMMATORY, ANALGESICS, AND OPHTHALMIC DRUG PRODUCTS
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, Analgesics and Ophthalmic Drug Products
Attention: Document Room 115
9201 CORPORATE BLVD
Rockville, Maryland 20850

If you have any questions, call BARBARA GOULD, Regulatory Project Manager, at (301) 827-2504.

Sincerely,

{See appended electronic signature page}

CARMEN DEBELLAS, RPH
Division of Anti-Inflammatory, Analgesics
and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Barbara Gould
6/20/03 05:06:29 PM
for Carmen DeBellas, RPh

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