CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-042 / S-024
21-052 / S-017

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products

REGULATORY PROJECT MANAGER REVIEW

Application Numbers: NDA 21-042/S-024
NDA 21-052/S-017

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: November 21, 2003

Receipt Dates: November 24. 2003

Background and Summary

CBE supplements 024 and 017 provide for the addition of the adverse experience "constipation" to the Patient Product Information (PPI), based on WAES reports.

Review

The material used for the review of changes to the PPI consisted of the current labeling and the proposed labeling text for the PPI. 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 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 24 Nov. 2003

Barbara Gould
Regulatory Health Project Manager

Comment/Concurrence: *Carmen DeBellas, RPH 24 Nov. 2003*
Carmen DeBellas, RPH
Chief Project Management Staff

CSO LABELING REVIEW

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Barbara Gould
12/15/03 11:32:51 AM
CSO

Barbara Gould
12/15/03 11:34:34 AM
CSO
for Carmen Debellas, RPH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-024
NDA 21-042/S-017

CBE-0 SUPPLEMENT

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 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Numbers	Drug Name
21-042	024	Vioxx™ (rofecoxib tablets) 12.5 mg, 25 mg, and 50mg
21-052	017	Vioxx™ (rofecoxib suspension) 12.5 mg/5 mL, 25 mg/5 mL

Date of supplements: NOVEMBER 21, 2003
Date of receipt: NOVEMBER 24, 2003

These supplemental applications, submitted as "Supplement - Changes Being Effected" propose the addition of the adverse experience "constipation" to the Patient Product Information (PPI) based on WAES reports.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on JANUARY 24, 2004 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be MAY 24, 2004.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
DIVISION of Anti-inflammatory, Analgesic, & 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) 827-2506.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Barbara Gould
11/28/03 12:54:27 PM
for Carmen DeBellas, RPH