CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-042 / S-023

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Division of Anti-Inflammatory, Analgesic, & Ophthalmic Drug Products

REGULATORY PROJECT MANAGER REVIEW

Application Number: NDA 21-042/S-023

Name of Drug: Vioxx™ (rofecoxib) Tablets 12.5 mg, 25 mg, 50 mg

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

Material Reviewed:

Submission Date: June 27, 2003

Receipt Date: June 30, 2003

Background and Summary

Merck Research Laboratories (MRL) proposes to remove the "Day 1" and "Day 2" text from its package label for Vioxx™ 50 mg tablets. This decision came about during the review of the package label in preparation for the submission of a new NDA for rofecoxib for the treatment of acute migraine attacks (NDA 21-647, submitted to the Agency on May 23, 2003). In the migraine studies, over 90% of patient required only a single dose of Vioxx™. The statements concerning Day 1 and Day 2 are being removed to avoid misinterpretation by patients who may that they must take a 2-day course of Vioxx™.

Review

The material used for the review of changes to the package consisted of the current package for the 12.5 mg and 25 mg sample package. The sample package for the 12.5 mg and 25 mg use the text "ONCE DAILY" in association with the trade name Vioxx™ to indicate that the product is taken only once daily and refer patients to the accompanying circular for information on dosage.

The removal the "Day 1" and "Day 2" text upon review of its package will be consistent with the sample package for the 12.5 mg and 25 mg Vioxx™ package.

Conclusions

The supplement reviewed above was found to be acceptable. An approval letter should be issued to the Sponsor.

Barbara Gould
Barbara Gould
Regulatory Health Project Manager

Concurrence:

_____
Lourdes Villalba, M.D.
Medical Reviewer

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/s/

Barbara Gould
12/15/03 10:44:20 AM
CSO

Maria Villalba
12/15/03 11:49:18 AM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-023

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:

Name of Drug Product: Vioxx™ (rofecoxib) Tablets 12.5 mg, 25 mg, 50 mg
NDA Number: 21-042
Supplement number: 023
Date of supplement: JUNE 27, 2003
Date of receipt: JUNE 30, 2003

This supplemental application proposes the following change to remove the text "Day 1" and "Day 2" that appears on the VioxxTM that appears on the VioxxTM 50 mg sample packages.

All communications concerning this supplement should be addressed as follows:

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) 827-2506.

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
11/28/03 12:33:27 PM
for Carmen DeBellas, RPh