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:

Please refer to your supplemental new drug application dated June 27, 2003, received June 30, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VioxxTM (rofecoxib tablet) 50 mg.

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

We completed our review of this application, as amended. This application is approved, effective on the date of this letter to remove the text "Day 1" and "Day 2" from the Vioxx™ 50 mg sample packages.

Please submit final sample packaging for Vioxx™ 50 mg when it is available.

If you have any questions, call Barbara Gould, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Acting Director
Division of Anti-Inflammatory, Analgesic, &
Ophthalmic Drug Product
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Brian Harvey
12/16/03 11:32:03 AM