DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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

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 applications dated November 21, 2003, received November 24, 2003, 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

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.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the PPI. The PPI must be identical to the final patient product information contained in your submission dated November 21, 2003.

Please submit one copy of the final patient product information when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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 Division Director
Division of Anti-Inflammatory, Analgesic, &
Ophthalmic Drug Product
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/

Brian Harvey
12/16/03 10:30:24 AM