DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-028
NDA 21-052/S-021

Merck & Co., Inc.
Attention: Diane Louie, MD, MPH
Associate Director
Regulatory Affairs-Domestic
P.O. Box 2000, RY 33-200
Rahway, NJ 07065-0900

Dear Dr. Louie:

Please refer to your supplemental new drug applications dated March 16, 2004, received March 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx™ (rofecoxib) Tablets, 12.5 mg, 25 mg, and Suspension 12.5 & 25 mg/5 mL.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes in the *Labeling* Section under ADVERSE REACTIONS, Skin and Skin Appendages, to include "photosensitivity reactions" as a postmarketing adverse reaction and to revise the patient package information for consistency with the package circular to include "skin reactions caused by sunlight".

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the *Labeling* Section under ADVERSE REACTIONS, *Skin and Skin Appendages*, to include "photosensitivity reactions" as a postmarketing adverse reaction and include "skin reactions caused by sunlight" to the patient package information. These revisions are terms of the approval of these applications.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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) 827-2506.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Sharon Hertz

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