



NDA 21-042/S-018

NDA 21-052/S-012

Merck & Co., Inc.
Ned Braunstein, M.D.
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 October 14, 2002, received October 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
21-042	S-018	Vioxx (rofecoxib tablets) 12.5 mg, 25 mg, 50 mg
21-052	S-012	Vioxx (rofecoxib suspension) 12.5 mg/5 mL, 25 mg/5mL

We acknowledge receipt of your submissions dated January 05, February 20, March 05, and June 18, 2003.

These supplemental new drug applications provide for changes in the **CLINICAL PHARMACOLOGY, CLINICAL STUDIES, PRECAUTIONS, and DOSAGE AND ADMINISTRATION** sections. The package circular and patient package insert been revised to include a brief description of the aspirin endoscopy study and the maximum recommended dose for patients with moderate hepatic insufficiency.

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 agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-042/S-018, and NDA 21-052/S-012." Approval of these submissions by FDA is not required before the labeling is used.

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If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-2504.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic &
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

/s/

Lee Simon

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