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APPLICATION NUMBER:

21-042 /S-020, 021, 022
21-052 /S-014, 015, 016

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-020, 021, 022
NDA 21-052/S-014, 015, 016

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 submitted under section 505(b) Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Numbers	Drug Name
21-042	020, 021, 022	Vioxx™ (rofecoxib tablets) 12.5 mg, 25 mg, and 50mg
21-052	014, 015, 016	Vioxx™ (rofecoxib suspension) 12.5 mg/5 mL, 25 mg/5 mL

Date of supplement: December 11, 2002, May 05, 2003, and June 17, 2003

Date of receipt: December 12, 2002, May 07, 2003, and June 19, 2003

These "Changes Being Effected" supplemental new drug applications provide for the following:

Supplement 020 and 014 provide for changes to the Patient Product Information (PPI) to add colitis, and menstrual disorder to the Side Effect section for consistency with the current package circular.

Supplement 021 and 015 provide for changes to the Patient Product Information (PPI) to add ringing in the ears to the Side Effect section for consistency with the current package circular.

Supplement 022 and 016 provide for changes to the Package Circular to add post-marketing adverse experiences of aplastic anemia, pancytopenia, and epilepsy aggravated based on WAES reports. The Patient Product Information has been revised for consistency with the current package circular.

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.

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 supplements NDA 21-042/S-020, 021, 022 and NDA 21-052/S-014, 015, 016." Approval of these submissions by FDA is not required before the labeling is used.

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, Analgesics, &
Ophthalmic Drug Products
Office of Drug Evaluation V
Center 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/

Lee Simon
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