

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-042 / S-017

21-052 / S-011

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-042/S-017
NDA 21-052/S-011

Merck & Co. Inc.
Attention: Ned Braunstein, M.D.
Director, Regulatory Affairs
P.O. Box 2000, RY 33-720
Rahway, NJ 07065-0900

Dear Dr. Braunstein:

Please refer to your supplemental new drug applications dated April 23, 2003, received April 24, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vioxx (rofecoxib tablet), NDA 21-042 and Vioxx (rofecoxib oral suspension), NDA 21-052.

These supplemental new drug applications provide for addition of "hypertensive crisis, blurred vision, insomnia and severe increase in blood pressure to the labeling.

We completed our review of these applications. 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 submitted labeling package insert submitted April 23, 2002. 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 ten 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-017 and NDA 21-053/S-011 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, HF-2
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) 827-2040.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmics
HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Lee Simon
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