CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

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

CBE-0 SUPPLEMENT

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

Dear Dr. Braunstein:

We have received your supplemental drug applications 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-017	Vioxx (rofecoxib tablets) Tablets 12.5 mg, 25 mg, 50 mg
21-052	S-011	Vioxx (rofecoxib suspension) Suspension 12.5 mg/5 mL, 25 mg/5 mL

Date of Supplements: April 23, 2002

Date of Receipt: April 24, 2002

These supplemental applications submitted as "Supplement - Changes Being Effected" supplements, propose changes in the Labeling Section of the package circular and patient product information as follows:

1. Update of the copyright date
2. Inclusion of "hypertensive crisis", " severe increase in blood pressure", "blurred vision", and "insomnia" as post-marketing adverse experiences

Unless we notify you within 60 days of our receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the Act on June 24, 2002 in accordance with 21 CFR 314.101(a).

Please cite the application numbers listed above at the top of the first page of any communications concerning these applications. All communications concerning these supplemental applications should

be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Attention: Division Document Room
HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Attention: Division Document Room
HFD-550
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Barbara Gould, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
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/

Barbara Gould
5/13/02 08:25:06 AM
for Carmen DeBellas