Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

NDA 17-911/S-070

Merck & Co., Inc.
PO Box 1000, UG2CD-4B
North Wales, PA 19454-1099

Attention: Kenneth A. Kramer
Associate Director, Worldwide Regulatory Affairs

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated February 2, 2007, received February 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clinoril™ (sulindac) Tablets.

We acknowledge receipt of your submission dated April 9, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS**, **ADVERSE REACTIONS**, and **HOW SUPPLIED** sections of the package insert.

We have completed our review of this application, as amended, and it is 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 submitted labeling (patient package insert submitted April 9, 2007).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission "Final Printed Labeling for approved NDA 17-911/S-070." Approval of this submission by FDA is not required before the labeling is used. Upon receipt and verification, we will transmit this version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Product
Office of New Drugs II
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/

Bob Rappaport

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