DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 17-911/S-072

Merek & Co., Inc.
PO Box 1000, UG2CD-48
North Wales, PA 19454-1099

Attention: Kristin J. Rittenhouse
Manager, Worldwide Regulatory Affairs

Dear Ms. Rittenhouse:

Please refer to your supplemental new drug application dated November 21, 2008, received November 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clinoril (sulindac), Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the **ADVERSE REACTIONS: Hypersensitivity Reactions** section of the package insert and changes to the US Medication Guide.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling text (FPL) submitted on November 21, 2008.

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
Suite 12B05
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 Ayanna Augustus, Regulatory Project Manager, at (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Drugs
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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