DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-445/S-058

Merck & Co., Inc.
P.O. Box 1000, UG2CD-48
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 January 19, 2007, received January 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dolobid™ (diflunisal) Tablets.

This "Changes Being Effected" supplemental new drug application is submitted in response to the Agency's January 5, 2007, letter requesting revision to the DOLOBID™ Medication Guide to comply with the class-labeling changes for the NSAID 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 FPL submitted on January 19, 2007.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Education 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/

Bob Rappaport

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