DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-059/S-097
NDA 17-814/S-040
NDA 18-332/S-030

Merck & Co., Inc.
UG2CD-48
P.O. Box 1000
North Wales, PA 19454-1099

Attention: Kenneth A. Kramer
Associate Director, Regulatory Affairs

Dear Mr. Kramer:

Please refer to your supplemental new drug applications dated July 31, 2006, received August 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INDOCIN (indomethacin) Capsules (25 mg and 50 mg), Suppositories (50 mg) and Oral Suspension (25 mg per 5 mL).

We acknowledge receipt of your submissions dated December 18, 2006.

These supplemental new drug applications propose revising the pediatric dosage recommendations in the *Pediatric Use* portion of the PRECAUTIONS section of the package insert. You have also incorporated the NSAID class-labeling language in the Medication Guide.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, which includes a medication guide. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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. Upon receipt and verification, we will transmit that 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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

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 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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