



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-059/S-095
NDA 17-814/S-038
NDA 18-332/S-028

Kenneth A. Kramer
Manager, Regulatory Affairs
Merck Research Laboratories
BLA-20 P.O. Box 4
West point, PA 19486

Dear Mr. Kramer:

Please refer to your supplemental new drug applications dated October 1, 2004, received October 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Indocin (Indomethacin) Capsules, 25mg, 50mg, Suppositories, 50mg, and Oral Suspension, 25mg/5mL.

These supplemental new drug applications provide for addition of the language under **PRECAUTIONS**, *Drug Interactions*, the text "In post marketing experience, bleeding has been reported in patients on concomitant treatment with anticoagulants and INDOCIN. Caution should be exercised when INDOCIN and anticoagulants are administered concomitantly."

We completed our review of these applications. These applications are 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 submitted labeling package insert submitted October 1, 2004.

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, HFD-410
FDA
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 Kathleen Reedy, Regulatory Project Manager, at (301) 827-2533.

Sincerely,

{See appended electronic signature page}

Sharon S. Hertz, M.D.
Deputy Division Director
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
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/s/

Sharon Hertz

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