



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-878/S-018
NDA 18-878/S-019

Merck & Company, Inc.
Attention: Kenneth Kramer
Associate Manager, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your supplemental new drug applications dated December 7, 2001 and May 9, 2002, received, December 10, 2001 and May 13m 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Indocin I.V. (indomethacin injection).

Your submission of March 21, 2003 constituted a complete response to our November 5, 2002 action letter.

These "Changes Being Effected" supplemental new drug applications provide for multiple changes to the labeling.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 21, 2003.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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 Barbara Gould, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M. D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products,
HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Lee Simon

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