



NDA 50-517/S-046

Merck & Co., Inc.
Attention: Virginia G. Snyder, M.S.
Associate Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug application dated November 24, 2003, received November 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MefoxinTM Injection (cefoxitin sodium). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental application, submitted as "Supplement - Changes Being Effected," provides for:

Changes in the *Labeling* Section of the approved New Drug Application for MefoxinTM. The package circular has been revised under the INDICATIONS AND USAGE, PRECAUTIONS, General, and PRECAUTIONS, Information for Patients sections, according to the February 6, 2003 FDA Final Rule regarding "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (21 CFR Part 201).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 25, 2003.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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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 LT Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Labeling

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Janice Soreth
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