



NDA 50-517/S-042 and S-045

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

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated August 17, 2001 (S-042) and February 11, 2003 (S-045), received August 20, 2001 (S-042) and February 12, 2003 (S-045), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mefoxin™ (cefodoxitin) for Injection. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated December 2, 2002 (S-042), September 9, 2003 (S-045) and June 18, 2004. Your submission of December 2, 2002 (S-042) and September 9, 2003 (S-045) contained final printed labeling (FPL) constituted a complete response to our May 24, 2002 (S-042) and August 8, 2003 (S-045) action letter.

These supplemental new drug applications propose the following changes:

- a) NDA 50-517/S-042: The addition of a paragraph that provides pharmacokinetic information for the elderly under the **CLINICAL PHARMACOLOGY** section, and the addition of a *Geriatric Use* subsection under the **PRECAUTIONS** section in order to comply with the Final Rule on Geriatric Labeling.
- b) NDA 50-517/S-045: The addition of urticaria and flushing under **Post-Marketing Reports** in the **ADVERSE REACTIONS** section. Also, references to the diluents, "10 percent invert sugar in water" and "10 percent invert sugar in saline" solutions have been removed from the **DOSAGE AND ADMINISTRATION** section.

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 FPL submitted on December 2, 2002 (S-042) and September 9, 2003 (S-045).

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 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

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth
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