



NDA 50-347/S-052

Pharmacia & Upjohn  
a subsidiary of Pfizer, Inc.  
Attention: Corinne Gamper  
Director, World Wide Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Gamper:

Please refer to your supplemental new drug application dated October 23, 2003, received October 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trobicin<sup>®</sup> Sterile Powder (spectinomycin hydrochloride for injectable suspension, USP). 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 “Changes Being Effected” supplemental new drug application provides for revisions to the label to comply with the requirements set forth in CFR 201.24, “Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use.”

We note that references to the Trobicin Sterile Powder, 4-gram vial have been removed from the label and that the temperature range for the storage conditions have been changed. Please, provide information about these changes in your next annual report.

We completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 23, 2003.

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 Ms. Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Lillian Gavrilovich  
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