



NDA 50-435/S-008

Pfizer, Inc.  
Attention: Pritpal Nijjar  
Regulatory Manager  
235 East, 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Nijjar:

Please refer to your supplemental new drug application dated January 30, 2004, received February 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geocillin<sup>®</sup> (carbenicillin indanyl sodium), Tablets. 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.

We also acknowledge your submissions dated February 23, 2004 [containing final printed labeling (FPL)], and March 17, 2004.

This supplemental new drug application provides for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We have completed the review of this supplemental application and it is approved effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on February 23, 2004.

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 these NDA and a copy to the following address:

MEDWATCH, HF-2  
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 Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

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

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

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Lillian Gavrilovich  
12/23/04 10:58:31 AM  
Signing for Dr. Soreth.