



NDA 50-435/S-009

Pfizer Global Pharmaceuticals  
Attention: Beatrice Curran  
Associate Director, World Wide Regulatory Strategy  
235 East 42<sup>nd</sup> Street 685/18/16  
New York, NY 10017

Dear Ms Curran:

Please refer to your supplemental new drug application dated August 16, 2007 and received August 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geocillin<sup>®</sup> (carbenicillin indanyl sodium) Tablets.

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 new drug application has been submitted in response to an Agency letter requesting an update to the **WARNINGS** and **PRECAUTIONS** sections of the labeling concerning *Clostridium difficile* associated diarrhea (CDAD).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on August 16, 2007.

We note that your August 16, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 22, Room 4447  
Silver Spring, MD 20903

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If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Katherine A. Laessig, M.D.  
Deputy Director  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Evaluation and Research

Enclosure:

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/s/

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Kathrine Laessig  
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