



NDA 50-608/S-026

Pfizer, Inc.
Attention: Pritpal Nijjar
Regulatory Manager
Worldwide Regulatory Strategy
235 East 42nd Street
150/7/9
New York, NY 10017-5755

Dear Mr. Nijjar:

Please refer to your supplemental new drug application dated January 27, 2004, received January 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unasyn (ampicillin sodium/sulbactam sodium) for Injection. 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 receipt of your submission dated February 24, 2004.

This "Changes Being Effected" 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 our review of this application and it is approved effective on the date of this letter.

If a letter communicating important information about these drug products (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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Susmita Samanta, M.D., Regulatory 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
this page is the manifestation of the electronic signature.**

/s/

Lillian Gavrilovich
8/19/04 11:16:47 AM
Signing for Dr. Janice Soreth.