



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-608/S-029

Pfizer, Inc.
Attention: Priso Epale
Regulatory Manager
235 East 42nd street
New York, NY 10017

Dear Mr. Epale:

Please refer to your supplemental new drug application dated April 26, 2007, received April 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unasyn (ampicillin sodium, sulbactam sodium). 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 June 28, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **WARNINGS** and **PRECAUTIONS/Information for Patients** sections to include information on *Clostridium difficile associated disease (CDAD)*.

We completed our review of this application, as amended. This application 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 June 28, 2007.

We note that your June 28, 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 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-0803.

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 Drug Evaluation and Research

Enclosure: Labeling submitted on June 28, 2007

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

Kathrine Laessig
4/14/2008 02:42:54 PM