DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 23 2007

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Imtiyaz Basade
Vice President Regulatory Affairs
Orchid Healthcare
Plot Nos. B3-B6 & B11-B14, SIPCOT Industrial Park
Irungattukottai, Kancheepuram District – 602 105
India

Re: Docket No. 2006P-0442/CP1

Dear Mr. Basade:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 27, 2006. Your petition requests that the FDA (1) determine that the originally approved formulation (now discontinued) of Zosyn (piperacillin and tazobactam for injection) packaged in a 40.5-gram pharmacy bulk vial was not discontinued for safety or efficacy reasons; and (2) accept abbreviated new drug applications for piperacillin and tazobactam for injection, without edetate sodium dehydrate and citric acid monohydrate.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0442

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