DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 2 2006

William A. Rakoczy
Christine J. Siwik
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street
Suite 500
Chicago, IL 60610

Re: Docket No. 2006P-0195/CP1

Dear Mr. Rakoczy and Ms. Siwik:

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 May 9, 2006. Your petition requests that the FDA (1) determine that the originally approved formulation (now discontinued) of Zosyn (piperacillin and tazobactam for injection) was not discontinued for safety or efficacy reasons; and (2) accept abbreviated new drug applications for piperacillin and tazobactam for injection, 2.25 grams, 3.375 grams, and 4.5 grams, without edetate sodium and citric acid.

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-0195

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