



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY 4 2006

Beth Brannan  
Sandoz, Inc.  
2555 West Midway Blvd.  
P.O. Box 446  
Broomfield, CO 80038-0446

Re: Docket No. 2005P-0456/CP1 & SUP1

Dear Ms. Brannan:

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 November 8, 2005. Your petition requests that the FDA determine that the originally approved formulation (now discontinued) of Zosyn (piperacillin and tazobactam for injection) was not discontinued for safety or efficacy reasons.

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  
Associate Director for Policy  
Center for Drug Evaluation and Research

2005P-0456

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