DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 19 2006

Geoffrey M. Levitt
Wyeth Pharmaceuticals
P.O. Box 8299
Philadelphia, PA 19101

Re: Docket No. 2006P-0173/CP1, SUP1 & SUP2

Dear Mr. Levitt:

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 April 25, 2006. Your petition requests that any abbreviated new drug application or 505(b)(2) application referencing Zosyn (piperacillin and tazobactam for injection) (1) comply with the US Pharmacopeia standards on particulate matter in injectable drugs when tested under expected conditions of actual use; and (2) exhibit the same compatibility profile as Zosyn.

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-0173 LET 1