



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

APR 13 2012

Sidney M. Wolfe, M.D.  
Michael Carome, M.D.  
Public Citizen Health Research Group  
1600 20th Street, NW  
Washington, D.C. 20009

Re: Docket No. FDA-2011-P-0785

Dear Dr. Wolfe and Dr. Carome:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on October 28, 2011. Your petition requests that the Agency immediately require the addition of a black box warning, the distribution of an FDA-approved patient Medication Guide, and the distribution by Pfizer Pharmaceuticals, Inc. of a Dear Doctor letter for Tygacil (tigecycline) 50 milligrams/vial.

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,

A handwritten signature in cursive script that reads "Jane A. Axelrad".

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