



Food and Drug Administration  
Rockville MD 20857

JUN 4 2007  
0229 7 JUN -6 P3:09

Christopher J. Nascone  
Regulatory Affairs  
Vintage Pharmaceuticals, LLC  
150 Vintage Drive  
Huntsville, AL 35811

Re: Docket No. 2006P-0496/CP1

Dear Mr. Nascone,

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 by the Agency on December 4, 2006. Your petition requests that we determine whether the Azo Gantanol, Azo Gantrisin, and Sulfamethoxazole, Trimethoprim, and Phenazopyridine HCl drug products were withdrawn from the market for reasons of safety or effectiveness.

We have been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

2006 P- 0496

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