DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 13 2007

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Mark Moyer
Vice President, U.S. Deputy Head,
Regulatory Development
Sanofi Aventis US LLC
9 Great Valley Parkway
Malvern, PA 19355-1304

Re: Docket No. 2006P-0523/CP1

Dear Mr. Moyer:

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 December 20, 2006. Your petition requests that the Agency require applicants referencing Eloxatin solution (oxaliplatin injection) to demonstrate through preclinical and/or clinical testing that any new compound resulting from the addition of an acid (other than oxalic acid), or conjugate base thereof, to oxaliplatin does not compromise the safety or efficacy of the drug product.

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

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