DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 22 2006

Food and Drug Administration
Rockville MD 20857

Stephen A. Campbell, Esq.
Senior Vice President, Regulatory Affairs
Amphastar Pharmaceuticals, Inc.
11570 6th Street
Rancho Cucamonga, CA 91730

Re: Docket No. 2006P-0092/CP1

Dear Mr. Campbell,

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 March 1, 2006. Your petition requests that we declare Astra Zeneca's Diprivan, Teva Sicor's propofol injectable emulsion, and Bedford Laboratories' propofol injectable emulsion misbranded under the Federal Food, Drug, and Cosmetic Act because their labeling states that the products contain no preservatives.

We have 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-0092

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