DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 2 2007

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David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner LLP
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007-5143

Re: Docket No. 2006P-0311/CP1

Dear Mr. Rosen,

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 August 7, 2006. Your petition requests that we investigate and take appropriate regulatory action to ensure that the use of Bedford Laboratories' propofol injectable emulsion product will not expose patients to an unreasonable risk of infection due to the product's alleged inability to adequately inhibit microbial growth.

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-0311

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