DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 22 2007

Ms. Melissa A. Nguyen
Manager, Global Regulatory Affairs
Hospira, Inc.
275 North Field Drive
Dept. 389, Bldg. H2-2
Lake Forest, Illinois 60064

Re: Docket No. 2006P-0360/CP1

Dear Ms. Nguyen:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition that you submitted on behalf of Hospira, Inc. (Hospira) dated August 25, 2006. In the petition you request a determination by FDA that the originally approved and now discontinued formulation of Eastman Kodak's Carbocaine Injection, 3%, supplied in a 1.8 milliliter (mL) cartridge, was not discontinued for safety or efficacy reasons and is not less safe or effective than Eastman Kodak's currently marketed Carbocaine product.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities and the complexity of the issues raised by your petition, which require additional review and analysis by the Agency. 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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