



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 19, 2013

Gordon Johnston
Gordon Johnston Regulatory Consultants, LLC
3631 Martins Dairy Circle
Olney, MD 20832

Dear Mr. Johnston:

Your petition to the Food and Drug Administration requesting the Agency to determine whether Leucovorin Calcium Injection-Preservative Free, 10 mg/1mL, 10 mL total fill volume (ANDA 40147) held by Hospira has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy, was received by this office on 12/17/2013. It was assigned docket number FDA-2013-P-1654/CP1, and it was filed on 12/19/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Karen Kennard", is written above the typed name.

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)