DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 12, 2019

Brian J. Malkin
Arent Fox LLP
1717 K Street, NW
Washington, DC 20006-5344

Sent via email to: brian.malkin@arentfox.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner determine whether the Reference Listed Drug Tham Solution (Tromethamine Injection), New Drug Application No. N013025, held by Hospira Inc, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or efficacy reasons was received by this office on 01/30/2019.

It was assigned docket number FDA-2019-P-0692. 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,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.02.13 13:19:31 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)