DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 27, 2013

David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner LLP
3000 K Street, NW, 6th Floor
Washington, DC 20007-5143

Dear Dr. Rosen:

Your petition to the Food and Drug Administration requesting the determination that Cytoxan® (cyclophosphamide) for Injection, originally approved by FDA as a lyophilized powder under NDA 12-142 has been voluntarily withdrawn from sale for safety or effectiveness reasons, was received by this office on 2/27/2013. It was assigned docket number FDA-2013-P-0241/CP1, and it was filed on 2/27/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)