



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

February 27, 2013

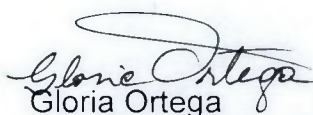
David L. Rosen, B.S. Pharm., J.D.  
Foley & Lardner LLP  
3000 K Street, NW, 6<sup>th</sup> Floor  
Washington, DC 20007-5143

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for Injection, originally approved by FDA as a lyophilized powder under NDA 12-142 has been voluntarily withdrawn from sale for safety or effectiveness reasons, was received by this office on 2/27/2013.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)