



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 6, 2020

Diana Sloane
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Sent via email to: d.sloane@lachmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine that all discontinued formulations of all strengths of Cytosan (cyclophosphamide) Injection approved under NDA 012142 were not withdrawn for reasons of safety or efficacy was received by this office on 05/05/2020.

It was assigned docket number FDA-2020-P-1344. 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
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)