October 12, 2023

Diana Sloane
Senior Associate
Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

October 12, 2023

Re: Docket No. FDA-2020-P-1344

Dear Ms. Sloane:

This letter responds to your citizen petition received on May 5, 2020, requesting that the Food and Drug Administration (FDA) determine whether all discontinued formulations of all strengths of Cytoxan (cyclophosphamide) Injection, approved under new drug application 012142, have been withdrawn for reasons of safety or efficacy. The citizen petition specifically requested a determination for the "dry powder excipient free formulation of the 500 mg/vial, 1gm/vial, and 2gm/vial strengths."

FDA had previously determined that certain Cytoxan (cyclophosphamide) for Injection formulations and strengths were not discontinued from sale for reasons of safety or effectiveness, but these determinations did not address all previously approved formulations and strengths. In the Federal Register of March 1, 2004 (69 FR 9630), FDA issued a determination that Cytoxan (cyclophosphamide) for Injection (non-lyophilized formulation), 2 gram (g)/vial, was not withdrawn from sale for reasons of safety or effectiveness. In the Federal Register of August 5, 2013 (78 FR 47321), FDA issued a determination that Cytoxan (cyclophosphamide) for Injection (lyophilized formulations), 100 milligrams (mg)/vial, 200 mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial, and Cytoxan (cyclophosphamide) for Injection (non-lyophilized formulations), 100 mg/vial and 200 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records for certain other formulations of Cytoxan (cyclophosphamide) Injection and determined that the sterile dry powder excipient-free formulation of Cytoxan (cyclophosphamide) for Injection, 500 mg/vial, 1 gram g/vial, and 2 g/vial, and the sterile dry powder with sodium chloride formulation of Cytoxan (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, were not withdrawn from sale for reasons of safety or effectiveness.

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (202) 768-5659.

Sincerely,

Tereza Y. Hess -S

Digitally signed by Tereza Y. Hess -S
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Tereza Hess
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure