April 14, 2023

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZENS PETITION – REVIEW AFFIRMATION REQUEST

RE: FDA-2013-P-0769

Dear Sir or Madam:

Lachman Consultants Services, Inc. hereby confirms that Suitability Petition submitted on June 18, 2013; assigned Docket number FDA-2013-P-0769 for Bendamustine for Injection, 200 mg/vial should remain active and we request that the Office of Generic Drugs review and respond to this suitability petition as soon as possible. This request is being made in response to the letter dated March 17, 2023, from the Office of Generic Drugs requesting that Lachman Consultant Services, Inc. confirm whether the petitioner remained interested in a response for this petition.

The Suitability Petition was submitted pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with 21 CFR § 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to make a determination that Bendamustine for Injection, 200 mg/vial, which differs in strength compared to the RLD cited in the petition, is suitable for submission as an ANDA.

Please advise if additional information is required.

Sincerely,

Martin Shimer Digitally signed by Martin Shimer
Date: 2023.04.14 07:27:20 -04'00'

Martin Shimer
Executive Director, Regulatory Affairs