

August 29, 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 – WITHDRAWAL REQUEST

RE: FDA-2019-P-1318

Dear Sir or Madam:

Lachman Consultants Services, Inc. hereby requests to withdraw the Suitability Petition submitted on March 19, 2019 and assigned Docket number FDA-2019-P-1318 for Paclitaxel for Injection Suspension, 200 mg/vial. This request is being made without prejudice to future submission.

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 Paclitaxel for Injection Suspension, 200 mg/vial which differs in strength in comparison to the RLD cited in the petition, is suitable for submission as an ANDA

Please advise if additional information is required in order to complete this withdrawal request.

Sincerely,

Martin H. Shimer
Executive Director, Regulatory Affairs
Lachman Consultant Services, Inc.