November 17, 2022

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-2013-P-0813

Dear Sir or Madam:

Lachman Consultants Services, Inc. hereby requests to withdraw the Suitability Petition submitted on July 2, 2013; assigned Docket number FDA-2013-P-0813 for Hydrocodone Bitartrate and Acetaminophen Tablets USP, 4 mg/300 mg, 6 mg/300 mg, and 8 mg/300 mg. 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 Hydrocodone Bitartrate and Acetaminophen Tablets USP, 4 mg/300 mg, 6 mg/300 mg and 8 mg/300 mg, which differs in the strength of hydrocodone bitartrate component 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 Shimer
Digitally signed by Martin Shimer
Date: 2022.11.17 09:33:00 -05'00'

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