

November 9, 2020

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-2020-P-2004

Dear Sir or Madam:

Lachman Consultant Services, Inc. hereby requests to withdraw the Citizen Petition submitted on September 23, 2020; assigned Docket number FDA-2020-P-2004.

The Citizen 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 designate ANDA 062488 listed in the Orange Book for Neomycin and Polymyxin B Sulfates and Hydrocortisone (Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate) Otic Suspension/Drops, 1% Eq. 3.5 MG Base/mL; 10,000 units/mL, as a RS for the purpose of submitting an ANDA for a generic version of the drug product.

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

Sincerely,

Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.