



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 25, 2020

Michelle Ryder
Lachman Consulting Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Sent via email to: m.ryder@lachmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate ANDA 040433 listed in the Orange Book for Lidocaine Hydrochloride Topical Jelly, 2%, as a RS for purposes of submitting an ANDA for a generic version of the drug product was received by this office on 09/24/2020.

It was assigned docket number FDA-2020-P-2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)