DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

April 06, 2020

David L. Rosen
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3000 K Street, N.W., Suite 600
Washington, DC 20007-5143

Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to allow the submission of an ANDA Suitability Petition for Lidocaine Hydrochloride Injection USP, 20mg /2mL (10mg/mL), 2 mL Fill vials (total vial content 20mg) pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93 was received by this office on 04/06/2020.

It was assigned docket number FDA-2020-P-1252. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2020.04.06 12:53:31 -04'00'

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