DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 4, 2020

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA designate the approved Prochlorperazine Maleate Tablets USP, 10 mg (A040268) of Jubilant Cadista Pharmaceuticals Inc., as a RS or designate a suitable alternative RS, upon which ANDA applicant can rely for purpose of in vivo bioequivalence testing required for ANDA filing was received by this office on 01/22/2020.

It was assigned docket number FDA-2020-P-0598. 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: 2020.02.04
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Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)