DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 26, 2019

J. Ben Haas
Latham & Watkins LLP
555 Eleventh Street, NW Ste. 1000
Washington, DC 20004-1304

Sent via email to: *ben.haas@lw.com*

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA expedite its review of Par's pending Prior Approval Supplments ("PASes") that seeks to eliminate an overage of the active ingredient in Adrenalin ® and to make attendant changes to the product's shelf life was received by this office on 12/20/2019.

It was assigned docket number FDA-2019-P-6044. 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: 2019.12.26 16:05:49 -05'00'

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