DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

September 26, 2019

David L. Rosen, BS Pharm., JD
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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 designate Reference Standard (RS) status for Propranolol Hydrochloride Tablets USP 80 mg, held by Watson Laboratories Inc. (ANDA No. 070178) was received by this office on 09/26/2019.

It was assigned docket number FDA-2019-P-4515. 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,

Karen Malvin Digitally signed by Karen Malvin
Date: 2019.09.26 19:33:22 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)