DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 18, 2020

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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 the FDA designate Reference Standard status for Warfarin Sodium Tablets USP 10 mg, held by Taro Pharmaceutical Industries Ltd. (ANDA No. 040301) was received by this office on 09/17/2020 and it was assigned docket number FDA-2020-P-1878.

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: 2020.09.18 15:26:21 -04'00'

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