



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 8, 2019

Chad Landmon
Axinn
950 F Street NW
Washington, DC 20004

Sent via email to: clandmon@axinn.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner to take prescribed actions with respect to any abbreviated new drug application (ANDA) for Phytonadione Tablets that references the reference listed drug ("RLD") Mephyton® (NDA No. 010104) was received by this office on 05/06/2019.

It was assigned docket number FDA-2019-P-2240. 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
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office Operations (OO)