DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 20, 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate both Doxycycline Hyclate for Injection, 100 mg Base/Vial and 200 mg Base/Vial, approved under ANDA 062475 as RLDs2 for purposes of FDA evaluation of ANDAs for Doxycycline Hyclate for Injection, 100 mg Base/Vial and 200 mg Base/Vial, containing mannitol as an excipient was received by this office on 05/19/2020.

It was assigned docket number FDA-2020-P-1403. 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: 2020.05.20 09:45:37 -04'00'

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