DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 12, 2020

Clark L. Anderson, M.D.
(b) (6)

Sent via email to: a(b) (6)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA revoke approval of the drug tolvaptan for the treatment of autosomal dominant polycystic kidney disease (ADPKD) was received by this office on 02/12/2020.

It was assigned docket number FDA-2020-P-0763. 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: 2020.02.13 09:27:57 -05'00'

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