



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

April 3, 2020

Mark Miles

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your petition demanding the Food and Drug Administration Commissioner issue proper warnings related to causal mechanisms for drugs with noted mechanisms of actions that lead to the adverse medical condition known broadly as nephrotic syndrome (also known as nil disease, minimal change disease, podocytopathies, and a variety of other named medical conditions where proteins are lost through the urine) was received by this office on 03/31/2020.

It has been assigned docket number FDA-2020-P-1248. 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 Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)