



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

August 4, 2020

Kurt R. Karst  
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Washington, DC 20005-5929

Sent via email to: [kkarst@hpm.com](mailto:kkarst@hpm.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA declare that the drug products Loperamide HCl Capsules, 1 mg and 4 mg, are suitable for consideration in an Abbreviated New Drug Application was received by this office on 08/03/2020.

It was assigned docket number FDA-2020-P-1730. 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 and 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)