



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 26, 2019

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
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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 declare that the drug product, Tramadol Hydrochloride Tablets, 25 mg, is suitable for consideration in an Abbreviated New Drug Application (“ANDA”) was received by this office on 11/25/2019.

It was assigned docket number FDA-2019-P-5593. 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)