



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 11, 2020

Howard S. Suh, Partner
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New York, NY 10178

Sent via email to: HSuh@foxrothschild.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA designate ANDA 074754 (Ketorolac Tromethamine Tablets, 10 mg) held by Teva Pharmaceuticals USA Inc. as a Reference Standard for purposes of FDA evaluation of ANDAs for Ketorolac Tromethamine Tablets, 10 mg was received by this office on 02/11/2020.

It was assigned docket number FDA-2020-P-0745. 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)