DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

May 17, 2019

Timothy H. Kratz
Kratz & Barry LLP
1050 Crown Pointe Pkwy, Suite 500
Atlanta, GA 30338

Sent via email to: tkratz@kratzandbarry.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner designate Reference Standard status for Diclofenac Sodium, delayed release tablet, 75 mg, was received by this office on 5/15/2019.

It was assigned docket number FDA-2019-P-2407. 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

Digitally signed by Dynna Bigby
Date: 2019.05.17 12:38:38 -04'00'

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