DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 8, 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., 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 that FDA designate ANDA 074260 (Carbidopa and Levodopa Tablets, 25mg/250mg) held by Actavis Elizabeth LLC as a reference standard for purposes of FDA evaluation of ANDAs for Carbidopa and Levodopa Tablets, 25 mg/250 mg, 25 mg/100 mg, and 10 mg/100mg was received by this office on 01/08/2020.

It was assigned docket number FDA-2020-P-0129. 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
Digitally signed by Dynna Bigby
Date: 2020.01.08 16:46:18 -05'00'

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