Kurt. R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-5929

Re: Docket No. FDA-2020-P-0129

Dear Mr. Karst: July 6, 2020

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 8, 2020. Your petition requests that the Agency designate carbidopa and levodopa tablets, 25 milligrams (mg)/250 mg, approved under abbreviated new drug application (ANDA) 074260 held by Actavis Elizabeth LLC or another appropriate ANDA as a reference standard for purposes of FDA evaluation of ANDAs for carbidopa and levodopa tablets, 25 mg/250mg, 25 mg/100 mg, and 10 mg/100 mg.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2020.07.06 08:47:45 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research