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BY ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

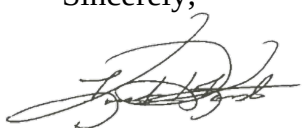
RE: Docket No. FDA 2020-P-0129

Dear Sir or Madam:

We write to follow-up on the Citizen Petition submitted on January 8, 2020 under Docket No. FDA 2020-P-0129 requesting that U.S. Food and Drug Administration (FDA), designate as a Reference Standard (RS) in its *Approved Drug Products With Therapeutic Equivalence Evaluations* carbidopa and levodopa tablets, 25 milligrams (mg)/250 mg, approved under abbreviated new drug application (ANDA) 074260 and held by Actavis Elizabeth LLC (or another appropriate ANDA). While FDA provided an interim response to the Citizen Petition on July 6, 2020, we remain eager to receive a substantive response to this Petition.

In the eleven months since the submission of the Citizen Petition, the current RS, Sinemet (carbidopa and levodopa tablets, 25 mg/250 mg) approved under NDA 017555, still has not become commercially available. Putative generic sponsors still are unable to obtain samples, which continues to shield Sinemet from additional generic competition. This situation is unlikely to resolve in the near future. As such, we urge FDA to designate a new RS for carbidopa and levodopa tablets, 25 mg/250mg, 25 mg/100 mg, and 10 mg/100 mg, immediately and expedite action on the Citizen Petition under Docket Number FDA 2020-P-0129 in an effort to facilitate further generic competition.

Sincerely,



Kurt R. Karst