LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600

FACSIMILE
(202) 737-9329

www.hpm.com

KURT R. KARST

Direct Dial (202) 737-7544
kkarst@hpm.com

November 10, 2020

BY ELECTRONIC SUBMISSION

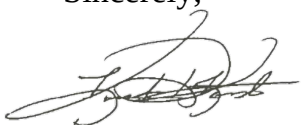
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

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

Dear Sir or Madam:

Petitioner has become aware of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard ("RS"). Because the controlled correspondence pathway is now available, Petitioner requests withdrawal of the above-referenced citizen petition requesting that, due to market unavailability of the current RS, FDA designate as a new RS 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). As such, a formal response to Docket No. FDA-2020-P-0129 is no longer necessary.

Sincerely,



Kurt R. Karst