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VIA ELECTRONIC DELIVERY

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

Re: Request to Withdraw Citizen Petition, Docket No. FDA-2019-P-5403

The undersigned (“Petitioner”) hereby withdraws its Citizen Petition, dated November 14, 2019, requesting that the U.S. Food and Drug Administration (“FDA”) amend the Approved Drug Products with Therapeutic Equivalence Evaluations to designate Abbreviated New Drug Application No. 065049 as a Reference Standard drug. FDA assigned Docket No. FDA-2019-P-5403 to this Citizen Petition. Petitioner requests withdrawal of its petition without prejudice, subject to 21 C.F.R. § 10.30(g).

If you have any questions or require additional information, please contact me by telephone at (202) 378-2306.

Very truly yours,

HUSCH BLACKWELL LLP

By: 

Seth A. Mailhot
Partner