



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 15, 2019

Seth A. Mailhot
Partner
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Sent via email to: seth.mailhot@huschblackwell.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to designate Abbreviated New Drug Application (ANDA) No. 065049 (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)) as a Reference Standard (RS) drug was received by this office on 11/14/2019.

It was assigned docket number FDA-2019-P-5403. 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,

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)