Seth A. Mailhot
Husch Blackwell LLP
750 17th St. N.W., Suite 900
Washington, DC 20006

Re: Docket No. FDA-2019-P-5403

Dear Mr. Mailhot: May 6, 2020

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on November 14, 2019. Your petition requests that the Agency designate the product approved under abbreviated new drug application (ANDA) 065049 held by Perrigo New York Inc. as a Reference Standard (RS) for Clindamycin phosphate topical solution 1% (Pledgets) in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) for the purpose of FDA evaluation of ANDAs.

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 C.F.R. 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
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.05.05 10:19:20 -04'00'

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