Pooja Kulkarni
GM, Regulatory Affairs
Macleods Pharmaceuticals Limited
G-2, Mahakali Caves Road, Shanti Nagar
Andheri (East), Mumbai - 400093
INDIA

Re: Docket No. FDA-2019-P-4481 April 29, 2020

Dear Ms. Kulkarni:

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 September 25, 2019. Your petition requests that the Agency designate the product approved under abbreviated new drug application (ANDA) 064050 held by Perrigo New York Inc. as a Reference Standard (RS) for Clindamycin phosphate topical solution 1% in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) upon which ANDA applicants can rely for purpose of *in vivo* bioequivalence testing, or that it designate a suitable alternative RS.

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: 2020.04.28 17:06:52 -04'00'

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