



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

September 25, 2019

Pooja Kulkarni  
GM, Regulatory Affairs  
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Andheri (East), Mumbai – 400093  
INDIA

*Sent via email to: [poojak@macleodspharma.com](mailto:poojak@macleodspharma.com)*

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to designate a suitable RLD/RS for purpose of submitting an ANDA application for Clindamycin topical solution 1% with reference to the current electronic orange book database (Approved Drug Products with Therapeutic Equivalence Evaluation) was received by this office on 09/25/2019.

It was assigned docket number FDA-2019-P-4481. 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,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Dockets Management Staff  
FDA/Office of Operations (OO)

Cc: [andrejg@macleodspharma.com](mailto:andrejg@macleodspharma.com)