



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 4, 2019

Bruce Thompson
Reguliance LLC
28 Hungerford Terrace
Burlington, Vermont USA 05401

Sent via email to: bthompson@Reguliance.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determine and declare that Solifenacin Succinate, 5 mg and 10 mg, Orally Disintegrating Tablets (ODT) is suitable for submission in an Abbreviated New Drug Application (ANDA) was received by this office on 10/04/2019.

It was assigned docket number FDA-2019-P-4645. 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 Officer
Dockets Management Staff
FDA/Office of Operations (OO)