

REGULIANCE



MILESTONES
TO
MARKETS

REGULATORY AFFAIRS AND PROJECT MANAGEMENT

September 20, 2023

Division of Dockets Management
Department of Health and Human Services,
Room 1061(HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

Docket Number FDA-2019-P-4645:

Subject: Withdrawal of ANDA Suitability Petition for Solifenacin Succinate, 5 mg and 10 mg, Orally Disintegrating Tablets (ODT)

Dear Sir or Madam,

As the US Agent for Intas Third Party Sales 2005, S.L. (Intas), located at Moll de Barcelona s/n, World Trade Center, Edifici Est, 6th Floor, 08039, Barcelona, Spain (named as INTAS from hereafter), with this letter I am hereby withdrawing, without prejudice, the ANDA Suitability Petition for Solifenacin Succinate, 5 mg and 10 mg, Orally Disintegrating Tablets (ODT) Docket Number FDA-2019-P-4645.

In accordance with your "Dear Petitioner" letter of August 17, 2023, concerning the impact of commitments in the GDUFA III Commitment Letter, we are notifying you that Intas is still interested in a response to the suitability petition and that we will be re-filing the petition after October 1, 2023.

Please do not hesitate to contact me by phone at 802-865-0261 or email bthompson@Reguliance.com to address any questions or concerns regarding this suitability petition withdrawal.

Sincerely,

Bruce Thompson

REGULIANCE LLC

28 Hungerford Terrace
Burlington, Vermont USA 05401
802.865.0261