

PRESS RELEASE

USFDA retains the OAI status of Indoco's Goa Plant I

Mumbai, April 24, 2019: The United States Food and Drug Administration (USFDA) retains the Official Action Indicated (OAI) status for Goa Plant – I (Finished Dosages Facility) of Indoco Remedies Limited. The facility was inspected by the USFDA in January 2019.

“We are in the process of sending our responses to the Regulators, as and when the commitments given in response to Form 483 observations are fulfilled. We believe that this OAI status will not impact our current commercial supplies to USA or revenues from this manufacturing facility. However, this may withhold approval of our pending ANDAs from this facility”, said Ms. Aditi Kare Panandikar, Managing Director, Indoco Remedies Limited.

The plant currently supplies against one approved ANDA and has four ANDAs pending for approval.

About Indoco Remedies Limited:

Indoco Remedies Ltd., headquartered in Mumbai, is a fully integrated, research-oriented pharma Company with presence in 55 countries. Indoco, a USD 161 million Company, employs over 5500 people including more than 300 skilled scientists.

The Company has 9 manufacturing facilities, 6 of which are for FDFs and 3 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by USFDA, UK-MHRA, TGA-Australia, MCC-South Africa, etc. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 70 million prescriptions annually from around 3,10,000 doctors belonging to various specialties. Indoco has 9 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Respiratory, Anti-Infective, Dental Care, Pain Management, Gastro-intestinal, Ophthalmic, Cardiovascular, Anti-Diabetics, Anti-Obesity, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Oxipod, Cital, ATM, Cloben-G, Sensiform, Sensodent-KF, Karvol Plus, Glychek, Tuspel Plus, etc. On the international front, Indoco has tie-ups with large generic companies like Watson (Actavis) – USA and ASPEN-South Africa.

For more details on Indoco, you may visit www.indoco.com

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