

PRESS RELEASE

Indoco's Goa Plant I receives Warning Letter from USFDA

Mumbai, July 15, 2019: Indoco Remedies has received a Warning Letter from The United States Food and Drug Administration (USFDA) for its Oral dosages Plant, situated at L -14, Verna Industrial Road, Goa (Plant I), as a result of the inspection carried out in January 2019. The facility had received 6 observations in Form 483s and was classified as 'OAI' (Official Action Indicated') in March, 2019. The Company responded to these observations with a detailed remediation plan, the implementation of which is still on-going.

Commenting on the development, Ms. Aditi Kare Panandikar, Managing Director, said that "We have already done considerable remediation work and shall continue to implement necessary additional corrective actions. We are committed to being cGMP compliant and supplying quality products to our customers and the patients across the globe."

The Company will respond to the Warning Letter within stipulated time and is already working with cGMP consultant to ensure that the remediation activities are completed in line with the USFDA's expectations.

The Company has one approved ANDA from this site, the annual revenue of which is around Rs. 3 crore. There are four pending ANDAs from this facility and these approvals may be withheld till all the issues are resolved.

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 140 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, Sensoform, Sensodent-KF, Karvol Plus, Glychek, Kidodent, Carmicide, Bactogard, 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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