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ASIA EDITION

Pharmaceutics International gets EIR from FDA

18 March 2019 | News

Pii has gained the FDA's approval of 4 sterile and non-sterile products

Pharmaceutics International, Inc. (Pii), a Contract Development and Manufacturing Organization (CDMO) has announced that the U.S. Food and Drug Administration (FDA) has issued their Establishment Inspection Reports (EIRs) for both FEI registration numbers (1000513101/3006503102), covering Pii's facilities in Hunt Valley and Cockeysville, MD. The EIRs are related to General and Pre-Approval Inspections (PAIs) that occurred between October 23rd and November 9th, 2018, of non-sterile and sterile drug production facilities.

Both EIRs indicate that Pii's facilities are at "voluntary action indicated" or VAI status, which means the Agency found Pii to be in an acceptable state of compliance. Subsequent to the FDA's inspection, and facility status recommendation, Pii has gained the FDA's approval of 4 sterile and non-sterile products.

"The successful completion of the FDA facility inspection is a very positive development for Pii, as we continue on our journey to meet and exceed U.S. and international regulatory requirements. Pii will continue to address observations noted during the inspection, and strive for the highest standard of product quality, compliance and customer service," said Dr. Kurt Nielsen, Pii's President and CEO.