Noramco Announces Submission of Drug Master File for Lisdexamfetamine Dimesylate – Active Pharmaceutical Ingredient

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Noramco, LLC, a leading North American producer of controlled substance bulk Active Pharmaceutical Ingredients (APIs) for the pharmaceutical industry, today announced it has submitted a Type II Drug Master File (DMF) to the U.S. Food and Drug Administration (FDA) for the active pharmaceutical ingredient lisdexamfetamine dimesylate (Lisdex/LDX). The DMF number is 035645. The FDA acknowledged receipt of the submission on November 23, 2021. Noramco has paid the DMF fee required under GDUFA and has completed GMP validation batches. Noramco is now advancing into commercial scale production in anticipation of growing demand from generic customers as the patent for the branded version of Lisdex nears expiry in 2023.

Lisdex is the API for Vyvanse®, the leading branded pharmaceutical product for the treatment of attention deficit hyperactivity disorder (ADHD), with FY 2019 annual sales surpassing $2.5 billion. Patient demand for the generic version is expected to be strong after the patent expires.

"As an established leader in the provision of controlled substance bulk APIs, advancing our ADHD API portfolio is one of our top priorities. This new DMF adds to our market-leading position in this category, allowing us to offer customers APIs for top-selling ADHD products including methylphenidate," said L. Lee Karras, Noramco Group Chief Executive Officer. "We are well positioned to supply significant quantities of Lisdex to generics customers, and customers can request samples now to qualify Lisdex from Noramco to use in their Abbreviated New Drug Application (ANDA) submissions for Vyvanse® generics. We are proud of our long-standing reputation for quality and our customers can proceed with their submissions secure in the knowledge they will not encounter issues with Noramco's DMF filings."

The company has the capability to manufacture up to 20 metric tons of Lisdex at its Wilmington, DE FDA-inspected GMP manufacturing site.

About Noramco, LLC

Noramco, headquartered in Wilmington, Delaware, is a leading North American producer of controlled substances bulk Active Pharmaceutical Ingredients (APIs) for the pharmaceutical industry. The company offers cannabinoids and clinical CDMO API services through its affiliate Purisys LLC, as well as many commercial APIs for use in abuse prevention, attention deficit hyperactivity disorders, pain management, and addiction management. Established in 1979, Noramco maintains production and R&D facilities in Delaware and Georgia (USA), and accesses agriculturally produced starting materials from Tasmania through an affiliate, Extractas Biosciences (fka Tasmanian Alkaloids). For more information, please visit www.noramco.com.

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