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Noramco introduces controlled substance development solutions at CPhI Worldwide

Frankfurt, Germany – Noramco is integrating its API development offering to include all of the technologies and services that generic and branded pharmaceutical producers require to advance solutions to market. The specialty API producer today introduced a comprehensive development-to-manufacturing platform to provide its customers more technically sound solutions, under one roof, with less complexity.

"Noramco has fine-tuned its business to serve as a solutions provider" said Jim Mish, CEO and President. "We now provide all of the expertise and assets that customers require to rapidly advance novel controlled API solutions from clinical to ready-to-implement commercial products," Mish said.

"We are here at CPhI Worldwide to showcase the pillars of our business that afford our customers the option to accelerate the development of their products in a flexible customer-friendly manner," said Bill Grubb, VP Global Strategy and Innovation. "The announcements we are making today provide the framework for Noramco as a one-stop resource for novel API development and unique dosage form solutions."

Dossier Development of Differentiated Products for Customers

Noramco--working with SPI Pharma--jointly announced a partnership at CPhI that brings together API and functional excipient science to deliver innovative patient-friendly solutions to formulators of finished dosage forms. This development service is an addition to the API services Noramco already supplies, which include formulation-friendly particle sizes, analytical data, and stability studies. "Our intention is to provide our customers with unique presentations, including all the elements of a full dossier, ready to manufacture at their facility," said Grubb.

Custom Synthesis of Controlled APIs

Most recently, Noramco upgraded its small-volume manufacturing suites in the United States. The flexible high-containment suites have controls in place to produce compounds of OEL<500 µg/m³. Special adaptions in-suite design, equipment design, operations and process safety afford developers a one-stop location to produce parenteral and high-potency controlled substances supported by a rapid response team to execute against client needs for clinical-to-commercial APIs.

New Controlled APIs

Noramco, a global controlled-API supplier with 40 years of experience, also continues to expand its portfolio of technologies to better serve the needs of its global customers. These include the amphetamine salts, methylphenidate hydrochloride and tapentadol hydrochloride as well as Cannabidiol, Dronabinol, and other related cannabinoids.

"One of the leading producers of specialty APIs, Noramco holds both the development and regulatory expertise required to bring virtually any controlled API to market, anywhere in the

world," Grubb said. "As we further expand our technology portfolio, our customers may come to us for APIs that address a greater diversity of medical conditions."

Distribution Partnership for Europe

Earlier this year Noramco announced a strategic framework to unlock the full potential of its business by expanding its portfolio and geographic reach to better align with market needs. To ensure generic and branded pharmaceutical product makers have access to the company's expanding portfolio and solutions services throughout Europe, Noramco has signed a letter of intent with Azelis, a value-adding distributor with expertise in controlled APIs. Azelis maintains application laboratories and warehouses throughout Noramco's European service area and is capable of accelerating product and reference standards delivery. Azelis joins existing distribution partners, Midas and IMCD.

Reference Standards Portfolio Now Available Online

Noramco offers well-characterized, highly purified analytical reference standards for routine analysis, method validation and development, commercial investigations, stability studies and other product development activities. Companies that hold a DEA license may now order impurity reference standards from Noramco directly online from a new highly secure website. This new website provides analysts, formulators, and developers rapid access to more than 175 reference standards products to accelerate their product development programs.

For more information about Noramco's controlled API product and service offerings, visit Noramco at CPhI during show hours, October 24-26, 2017 Stand 111A21, Frankfurt Messe, or on the web at www.noramco.com.

About Noramco

Noramco, headquartered in Wilmington, Delaware, is a leading North American producer of controlled substances and addiction treatment APIs for the pharmaceutical industry. The company offers products for use in attention deficit disorder, pain management, addiction management and abuse deterrence products. Established in 1979, Noramco maintains production and R&D facilities in Delaware and Georgia (USA); and Neuhausen, Switzerland; and accesses agricultural operations in Tasmania through an affiliate, Tasmanian Alkaloids.

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