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Pharmaceutics International, Inc.

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Pharmaceutics International, Inc. (Pii) – A Key Part of the FDA’s 503B Solution

Hunt Valley, MD (July 2, 2020) Pharmaceutics International, Inc. (Pii) has been added to the FDA’s list of organizations officially registered as human drug outsourcing facilities under the updated requirements of Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The prescribed use of customized, patient-specific drug compounds continues to grow in the United States. The FDA updated Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to advance its public health mission at the same time as innovative therapies transform modern healthcare best practices.

According to Dr. Kurt Nielsen, CEO of Pii, “the amendments to 503B of the FDCA are intended to provide a reliable supply of safe and effective medicines for hospitals and clinics to use for their patients.” The agility of the pharmaceutical outsourcing community has Nielsen feeling optimistic about “CDMOs and CMOs with appropriate capacities, capabilities to help alleviate drug shortages by bringing critical medicines, manufactured under stringent cGMP guidelines, to patients in need.” Pii will be actively working with hospital systems directly in all 50 states to mitigate drug shortages.

Nielsen feels especially hopeful that “patients, especially rare and orphan disease populations, will ultimately be better served by the pharma industry.” Medicines will be delivered in a dose and dosage form best suited for a patient’s disease and the needs of health-care providers at the point-of-care will be more effectively met.

For Pii the impact of 503B amendments has not been that significant. Pii has been operating under a set of best practices based on the health and pharma industries’ move toward a more patient-centric model. Many of Pii’s manufacturing suites are specifically designed for smaller batches and quick turn-over, and the scientific and engineering teams operate with a great deal of agility. Additionally, Pii has the Pharmaceuticals Know-how in formulation development

and testing of products, as well as, procurement of API and components from high quality suppliers.

More than 300 professional staff at Pii are proud to be part of the solution to bring improvements in care delivery to patients, physicians, and pharmacists, it is a responsibility taken seriously. Most of our staff have walked in the shoes of their clients and have a great deal of experience at the hard work of advancing medicines from discovery through commercialization and on to patients.

Nielsen likes to remind himself regularly that at Pii “we have families who rely on medicines to get through each day, and even some of us are patients. This is important to us, it’s our life’s work!”

To see the registry and learn more about it, along with changes to Sections 503A and 503B of Federal Food, Drug, and Cosmetic Act (FD&C Act), go to <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>

At Pharmaceutics International, Inc. (Pii), our motto is “challenges frame opportunities.” We are a contract development and manufacturing organization (CDMO) with a passion for problem-solving. Emphasizing collaboration, our experts complete projects on time with the highest quality standards, all from our Hunt Valley, Maryland campus.

Pii’s campus includes four cGMP and FDA inspected facilities, 70 manufacturing suites with all the necessary analytical testing capabilities on site, and four integrated aseptic filling suites delivering quality, safety, and efficiency. Experienced with small and large molecule compounds, we have special expertise in developing and manufacturing complex parenteral products, extended-release formulations, and non-aqueous injectable drug products. We can also overcome stability challenges with precision lyophilization cycle development and production.

Pii’s Pharmaceuticals Know-How™ can quickly and safely advance your drug from discovery through clinical testing to commercialization. Find out more at <https://www.pharm-int.com/>

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