



# News Release

## **Particle Sciences Expands Controlled Substance Capabilities with Approval of DEA Schedule I Registration**

CLEVELAND, May 28, 2019 –Particle Sciences, a Lubrizol LifeSciences company and pharmaceutical contract development and manufacturing organization (CDMO), has broadened its Drug Enforcement Administration (DEA) registration to become an authorized manufacturer of Schedule I substances. The expanded registration was granted following inspection by the DEA and will allow Particle Sciences to carry out analytical testing, development and manufacturing of cannabis-derived materials to be used in pharmaceutical applications for medically justified, legal uses in the United States.

Particle Sciences already has infrastructure in place to develop and manufacture Schedule II - V controlled drug products at its facility in Bethlehem, PA, and has worked on a number of projects in the past ranging from a novel nasal delivery system for diazepam to long-acting buprenorphine dosage forms. Under its new Schedule I registration, the company will build further on this infrastructure and open a new area of development for customers looking to take products through the traditional clinical trial and approval process.

Robert Lee, president of Particle Sciences states, "Particle Sciences has built a solid reputation and specialized expertise in controlled substances as a result of our team's work in complex formulations with substances in Schedules II - V." Lee continues, "A high level of ethical standards and water-tight controls/processes including accurate documentation are essential to carry out controlled substances work and these are already firmly ingrained in our day-to-day operations."

In 2018, the U.S. Food and Drug Administration (FDA) approved its first cannabis-derived drug, Epidiolex, for the treatment of seizures associated with two rare and severe forms of epilepsy. It has since announced a series of significant steps to develop a regulatory pathway for cannabis-derived products, including the formation of a high-level internal agency working group.

Barbara Morgan, general manager of Particle Sciences comments "The Schedule I registration will open up opportunities for us to work with clients with appropriate sources of controlled substances to further investigate the therapeutic value and effects of these compounds and help shape this emerging area of medicine."

The expanded registration is the latest step in Particle Sciences' broadening of its manufacturing capabilities as part of a wider investment by Lubrizol LifeSciences. The company recently opened a new commercial facility to accommodate production of complex sterile and non-sterile finished drugs and appointed new vice president of operations, Karen Bossert.

For further information, please visit: [www.particlesciences.com](http://www.particlesciences.com).

### **About Particle Sciences**

Particle Sciences, a Lubrizol LifeSciences company, is an integrated provider of drug development services. Particle Sciences focuses on BCS II/III/IV molecules, biologics and highly potent compounds through a variety of technologies including emulsions, gels, micro and nano-particulates, drug/device combination products, solid solutions and others. Particle Sciences is FDA registered and DEA licensed. Through a full range of formulation, analytic and manufacturing services, Particle Sciences provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic. The company was founded in 1991 and is headquartered in Bethlehem, Pennsylvania.

### **About Lubrizol LifeSciences**

Lubrizol LifeSciences is a preferred Contract Development and Manufacturing Organization (CDMO) partner for complex pharmaceuticals and innovative medical devices providing differentiated polymers and excipients, along with state-of-the-art design, development and manufacturing services to the healthcare industry.

### **About The Lubrizol Corporation**

The Lubrizol Corporation, a Berkshire Hathaway company, is a market-driven global company that combines complex, specialty chemicals to optimize the quality, performance and value of customers' products while reducing their environmental impact. It is a leader at combining market insights with chemistry and application capabilities to deliver valuable solutions to customers in the global transportation, industrial and consumer markets. Lubrizol improves lives by acting as an essential partner in our customers' success, delivering efficiency, reliability or wellness to their end users. Technologies include lubricant additives for engine oils, driveline and other transportation-related fluids, industrial lubricants, as well as additives for gasoline and diesel fuel. In addition, Lubrizol makes ingredients and additives for home care, personal care and skin care products and specialty materials encompassing polymer and coatings technologies, along with polymer-based pharmaceutical and medical device solutions.

With headquarters in Wickliffe, Ohio, Lubrizol owns and operates manufacturing facilities in 17 countries, as well as sales and technical offices around the world. Founded in 1928, Lubrizol has approximately 8,700 employees worldwide. Revenues for 2018 were \$6.8 billion. For more information, visit [Lubrizol.com](http://Lubrizol.com).

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