Halo Pharma Announces the Formation of its Pediatric Center of Excellence for the Development, Reformulation, and Manufacturing of Drug Products in Pediatric Dosage Forms

Top Pharmaceutical/Biotech Companies Come to Halo Pharma for Pediatric Dosage Forms

Whippany, NJ, May 10, 2017 - Halo Pharma announces the formation of its Pediatric Center of Excellence in support of the development and manufacture of dosage forms tailored for pediatric indications. Halo Pharma has been working closely with pharmaceutical companies to apply its extensive expertise in formulation sciences and its fully integrated manufacturing capabilities across a broad range of scales and dosage forms to overcome the challenges in developing pediatric dosage forms (PDFs) of already approved adult dosage forms. Halo Pharma is proud to be the manufacturer of choice for many of today's largest pharma companies having been selected to reformulate multiple products across a variety of dosage forms. Companies have come to rely on Halo Pharma as a trusted partner to provide specialized contract development and manufacturing services that meet the regulatory requirements of the U.S., Canada, and Europe, where Halo Pharma is already manufacturing PDFs for commercial sale through its sponsors.

Pharmaceutical companies are often asked by the U.S Food and Drug administration to conduct clinical trials for pediatric indications of adult dosage forms. The advantages of developing PDFs include the potential for extended patent protection and to obtain expanded indications in pediatric populations.

In support of its Pediatric Center of Excellence, Halo Pharma has developed the infrastructure, process trains and equipment needed for efficient, cost-effective, and rapid production of small- to medium-scale cGMP clinical drug products that are used in pediatric clinical studies. Companies that partner with Halo Pharma benefit from close collaboration with our formulation scientists who provide the technical expertise needed to modify adult dosage forms for pediatric use. This may include reformulation to enable a lower strength or making changes to the adult dosage form to improve patient compliance by making the medication easier to take and/or taste better.

Halo Pharma has partnered with several pharmaceutical companies already to develop commercially viable PDFs that have received both U.S. and international regulatory approvals. Halo Pharma currently has multiple clinical and commercial PDF programs underway. In nearly all cases, developing a PDF from an adult dosage form requires additional product development work. In many cases, it is necessary to provide the PDF in various strengths matched to different pediatric age/weight brackets. Halo Pharma has the capabilities to manufacture batches of PDFs that typically range in scale from 5 Kg to 1000 Kg, with many requiring multiple processing steps.

"Our formulation development and clinical manufacturing capabilities can support a variety of oral solid and liquid dosage forms suitable for pediatric applications, such as granules produced using fluid bed technology and mini-tablets that can be packaged into stick packs, powder in bottles for reconstitution, and our liquid products, which are typically oral solutions and suspensions that can also be time release-based," says Lee Karras, CEO of Halo Pharma. "We offer our customers over 40 years of commercial drug manufacturing experience and a proven track record of approvals with regulatory agencies around the world," Mr. Karras adds.

Halo Pharma can help your company develop, test, and bring to market pediatric dosage forms of your drug products quickly and cost effectively. To learn more about Halo Pharma's new Pediatric Center of Excellence visit www.Halopharma.com/pediatric.

ABOUT HALO PHARMACEUTICAL

Halo Pharmaceutical is a rapidly growing contract development and manufacturing organization (CDMO) that provides scientific and development expertise as well as a wide spectrum of manufacturing services from its locations in Whippany, New Jersey USA and Montreal, Quebec Canada to its international client base. Halo Pharma offers fully integrated capabilities in a variety of dosage forms including tablets, capsules, powders, liquids, creams, sterile and non-sterile ointments and suppositories. The company is registered to work with any of these dosages in the CI-CV DEA designations. Halo Pharmaceutical's capabilities in the areas of tech transfer, process and product development, production, scale-up/validation and analytical method development allow us to partner with clients from development through commercialization or at any point along the way. For more information please contact services@Halopharma.com.

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