Qualgen and FDA Reach Mutual Agreement

EDMOND, OKLAHOMA, US, December 20, 2022 /EINPresswire.com/ -- Qualgen is pleased to announce that, after several months of good-faith negotiations and cooperation, it has entered into a mutually agreed upon consent decree with the U.S. Food and Drug Administration (FDA) to maintain and improve upon the company's operational compliance with the Federal Food, Drug and Cosmetic Act (FDCA).

Qualgen Logo

The consent decree allows for more direct oversight of Qualgen moving forward and does not restrict it from operating or distributing its terminally sterilized products directly or indirectly.

Qualgen received a letter on December 19, 2022 from the FDA stating that based on Qualgen's prior submissions to the Agency, it is operating in a state of compliance and is, therefore, permitted to continue commercial production and distribution. The consent decree was negotiated in good-faith with FDA over a period of many months throughout 2022, during which time FDA never objected to Qualgen continuing to produce and distribute terminally sterilized drug products.

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>
> *Shaun Riney, Qualgen's chief executive officer*

Qualgen stands behind the safety of its products and is pleased to receive FDA's acknowledgment of its efforts to maintain and sustain compliance with federal regulatory requirements.

"Our dedicated associates have been diligently working in full cooperation with the FDA for approximately ten months (since early February 2022) in order to fully and finally resolve any

residual issues that have been identified by the FDA and brought to our attention. We have reached an agreement on a consent decree with FDA that we believe demonstrates our strong commitment to remaining compliant with cGMP requirements, while recognizing the significant public health service that our products provide to consumers. We have achieved this with no operational shut-down or interruption of our product supply to the patients that depend upon our products," Shaun Riney, Qualgen's chief executive officer, said. "We have already received FDA's initial notice regarding its positive views of our current state of compliance – this fact alone hopefully demonstrates that our firm is fully committed to providing safe products to the patients that need them. The FDA's reaction is consistent with its prior years of surveillance activity regarding Qualgen as there has never been a concern associated with any of our products that FDA raised to the level of a public health and/or safety issue. The FDA has been, and still is, in full communication with Qualgen at all times, specifically those times prior to, during, and following negotiation of the consent decree. We wholeheartedly appreciate the efforts of the Agency and the efforts of our tireless staff to achieve a state of compliance that justifies the continued compounding operations of Qualgen in abated fashion. As we understand it, the FDA's concerns were with operational compliance, which as demonstrated by FDA's December 19, 2022 letter, have been addressed or corrected, thus justifying Qualgen's continued operations."

Upon entry of the consent decree yesterday, the FDA immediately provided Qualgen with the aforementioned confirmation of its regulatory compliance with Current Good Manufacturing Practices (CGMP) regulations for finished pharmaceuticals and documented that FDA did not object to the company continuing to compound its terminally sterilized compounded drug products in accordance with all other requirements of the consent decree.

"We are excited to put this significant compliance achievement behind us and come out even stronger as an outsourcing facility with an uncompromising commitment to finished product quality and regulatory compliance. This experience certainly increased our awareness of FDA's expectations and helped us to forge a much more robust relationship with the FDA," Riney said.

ABOUT QUALGEN: Qualgen is a 503B outsourcing facility, that compounds sterile drugs and complies with all requirements of section 503B of the FDCA. Qualgen, a U.S. based company located in Edmond, Oklahoma, is a global leader in compounding pharmaceutical production. Founded in 2012, Qualgen offers numerous scientifically advanced compounds in multiple markets around the world.

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