December 17, 2024

Gelteq Receives FDA Approval of its Suitability Petition for New Animal Drug

Approval grants Gelteq fast track pathway for drug and entrance into the animal pharmaceuticals space

NEW YORK, Dec. 17, 2024 (GLOBE NEWSWIRE) -- Gelteq Limited (NASDAQ: GELS) ("Gelteq" or the "Company"), a clinical and biotechnology company focused on developing and commercializing white label gel-based delivery solutions for prescription drugs, nutraceuticals, pet care, sports, and other products, announces today that the U.S. Food and Drug Administration ("FDA") has approved its suitability petition for a new animal drug under development. The new animal drug leverages Gelteq's ingestible gel platform designed for nutrient and drug delivery. A suitability petition is a request by a drug sponsor to submit an abbreviated new animal drug application ("ANADA") for a proposed innovative new animal drug that differs from a previously FDA approved generic animal drug.

"We believe there is enormous opportunity for us in the animal pharmaceuticals market, as there is a significant need to deliver medications more efficiently," Gelteq co-founder and CEO Nathan Givoni said. "This pathway, which is essentially a faster track as opposed to the standard new animal drug application (NADA) pathway, is a strategic way for us to expedite our entry into the animal drug space and provide long-term value for all our stakeholders."

Gelteq has proposed changing the reference drug from a pill form into an oral gel form. These changes could be considered through the suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"). The FDA found that the proposed changes did not require Gelteq to conduct further investigations to show the safety and effectiveness of the innovative new animal drug for its intended uses. Therefore, the FDA approved the petition under section 512(n)(3)(C) of the FD&C Act which foregoes the safety and effectiveness studies and helps reduce the timeframe to reach potential approval of the new animal drug. This approval of the suitability petition, however, does not guarantee approval of the ANADA for Gelteq's proposed generic new animal drug.

About Gelteq Limited:
Headquartered in Melbourne, Australia, Gelteq (NASDAQ: GELS) is a clinical and biotechnology company that is focused on developing and commercializing white label gel-based delivery solutions for prescription drugs, nutraceuticals, pet care and other products. Gelteq is focused on advancing and commercializing its delivery solutions within five core verticals: pharmaceuticals, over-the-counter medications, nutraceuticals, animal medications, and sports nutrition. Gelteq's unique formulation directly addresses the issues associated with traditional drug delivery methods such as difficulty swallowing, taste of unpalatable ingredients, and dosage control. For more information, visit www.gelteq.com.

Forward-Looking Statements
Certain statements in this press release may constitute "forward-looking statements" within

the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “suggest,” “target,” “aim,” “should,” "will," “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Gelteq’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the timing and fulfilment of current and future orders relating to Gelteq’s products, the success of new programs, the ability to implement a new strategic plan and the success of a new strategic plan. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Gelteq in general, see the risk factors in the Annual Report on 20-F filed on November 15, 2024. All such forward-looking statements speak only as of the date they are made, and Gelteq undertakes no obligation to update or revise these statements, whether as a result of new information, future events or otherwise.

Contact:
CORE IR
516-222-2560
pr@gelteq.com

GELTEQ

Source: Gelteq Limited