Bubs Australia Limited
ACN 060 094 742
23-29 Nina Link, Dandenong South
VIC 3175 Australia

1800 2827 2878 (1800 BUBS AUST)
info@bubsaustralia.com

ASX ANNOUNCEMENT

BUBS SUBMITS CLINICAL TRIAL DATA TO US FDA

16 June 2025, Melbourne: Bubs Australia Limited (ASX:BUB) ("**Bubs**" or "**the Company**")

Bubs is pleased to confirm that it has formally lodged its New Infant Formula Submission (NIFS) with the US FDA (FDA) to cover all three Bubs infant milk formulas; goat, 365 day grass fed, and essential which are all currently sold in the US market.

The submission of the NIFS and the associated supporting data represents a critical and final milestone in Bubs' active participation in the FDA's formal regulatory pathway, and it is expected that the FDA will immediately commence its formal review of Bubs' NIFS.

At the end of Q2 FY25, Bubs completed its infant enrolment for the USA Clinical Trial with a total of 478 infants enrolled over 16 months. The Company has been conducting a large-scale clinical trial in the USA as part of its commitment to obtain permanent regulatory approval in the US market. Currently Bubs is one of only eight companies[1] permitted to operate under the FDA's "Enforcement Discretion" regulatory process.

Bubs' CEO Reg Weine said; "The submission of our NIFS represents an important milestone for Bubs in our journey to obtain permanent market access for the USA. With the USA already our biggest market and one in which we continue to see significant growth, it is pleasing to see that the overall regulatory progress remains firmly on-track. This remains one of the company's strategic pillars and will underpin future sustainable growth."

Bubs' COO Richard Paine commented "The successful completion of what is understood to be the largest single clinical infant milk formula trial in the world, is a testament to the technical and operational capabilities of Bubs and our partners in both Australia and the US. This submission represents an 'industry-first' for the Australian dairy industry and strongly positions Bubs as a globally credible manufacturer and brand"

Bubs expects formal notification from the FDA on permanent access by the end of the calendar year.

Footnotes
[1]The U.S. Food and Drug Administration's Long-Term National Strategy to Increase the Resiliency of the U.S. Infant Formula Market – January 2025

This release is approved by the Board of Directors.

END

MEDIA INQUIRIES

John Fergusson

John.fergusson@daymark.com.au

T 0407 862 952

SHAREHOLDER ENQUIRIES

(61 3) 9799 9988

Monday to Friday between 9am and 5pm (AEST)

investors@bubsaustralia.com

www.investor.bubsaustralia.com