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BUBS AUSTRALIA LODGES LETTER OF INTENT WITH FDA

FOR PERMANENT MARKET ACCESS IN USA TO OCTOBER 2025 AND BEYOND

- **U.S. Food and Drug Administration (FDA) releases clear regulatory pathway for permanent market access for Bubs® Infant Formula and seven other manufacturers that received enforcement discretion.**
- **Bubs Australia today confirms lodgement of the *Letter of Intent* for continued enforcement discretion for all six Bubs® Infant Formula products and commits to fully complying with applicable regulatory requirements within the timeframes stipulated.**
- **Bubs® Infant Formula range already satisfy USA nutrient requirements as per the U.S. Infant Formula Act for iron-fortified infant formula.**
- **Bubs® Infant Formula range will continue to be imported and seamlessly available on shelf for new and existing consumers in the USA throughout the transition period.**

Monday, 3 October 2022: Infant nutrition and dairy specialist Bubs Australia (ASX: **BUB**) today announced lodgement of the ***Letter of Intent*** to the **U.S. Food and Drug Administration (FDA)** as required under *FDA Guidance for Industry – Infant Formula Transition Plan for Exercise of Enforcement Discretion* (**Transition Plan**) issued on Saturday 1st October 2022 (Australian time). Bubs Australia is one of only eight infant formula manufacturers globally to receive FDA regulatory acknowledgement, enabling the safe import of all six Bubs® Infant Formula products under the enforcement discretion.

The Transition Plan is applicable only to those that have received the enforcement discretion and provides a clear regulatory pathway and framework of requirements for Bubs® Infant Formula to gain permanent access without interruption to supply to American families. The FDA intends to issue a Letter of Acknowledgement in response to the Letter of Intent, which if appropriate, will state that the enforcement discretion will be extended under the Transition Plan until October 2025, provided that the manufacturer continues to make meaningful progress toward compliance with the Transition Plan. Bubs intends to adhere to the new Infant Formula Requirements within the timeframe set out in the Appendix to this Announcement.

Bubs Founder and CEO, Kristy Carr said: "We are pleased to announce confirmation of our continued commitment to work with the U.S. Food and Drug Administration and welcome this important FDA announcement which provides a clear pathway for a select number of safe, nutritious, international infant formula brands to secure permanent regulatory approval.

"Since first receiving a green light from the FDA on 27 May 2022, allowing Bubs to import all six of our safe and clean infant formula products into the United States, we have worked closely with the Biden Administration,

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the U.S. Department of Health and Human Services, the FDA, and leading retailers across the country to ensure continued supply of Bubs Infant Formula were directed to those areas with the greatest need.

"Given the overwhelming positive response that we have received from American parents, caregivers, health care professionals and retailers, we are pleased to be able to commit that Bubs Australia will remain in the United States for the long term.

"This commitment and the FDA's announcement also mean American parents who are already safely using Bubs Infant Formula products, as well as our retail partners now stocking our formula in 6,500 stores across 42 states, can remain confident in ongoing supply, without interruption, providing more choices for American families seeking safe, clean nutrition for their children.

"Importantly, the FDA announcement also provides continued support for the ongoing expansion of our U.S. distribution footprint, as we look forward to launching Bubs Infant Formula products in various new retail groups in the months ahead," said Mrs Carr.

Bubs® Infant Formula range of clean, safe nutrition, including Bubs Supreme™ A2 Protein Cow Milk Formula, Bubs Organic® Cow Milk Formula, and Bubs® Easy-Digest Goat Milk Formula, are now ranged in 6,500 stores within the country's largest infant formula retailers; Walmart, Kroger, Albertson Safeway, Target, Whole Foods, Buy Buy Baby, Meijer, Hy-Vee, Thrive.com and Amazon.com (Prime).

Bubs Executive Chair, Dennis Lin, said: "Given Bubs Infant Formula products already satisfy all U.S. nutrient requirements, consumers can continue to have the highest level of confidence in the safety and quality of our products while we work with the FDA to complete the regulatory requirements.

"Our long-standing commitment to the United States means we are ready to move expeditiously to complete the FDA process outlined today by Commissioner Califf as we continue to expand our U.S. team and ramp up production.

"This, together with the other important regulatory milestone of the new SAMR GB registration pathway for Bubs China Label Infant Formula products, means we are truly placed in the ideal position of being able to access the world's top two infant formula markets – China and the USA. Once achieved, this will be a global first for any Australian or New Zealand company," said Mr Lin.

This release is approved by the Board of Directors.

END

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ABOUT BUBS AUSTRALIA LIMITED (ASX: BUB)

Founded in 2006 in Australia, Bubs' purpose is to grow happy, healthy families through clean nutrition. Bubs® A2 Beta-Casein Protein, Bubs Organic® Grass-fed, and Bubs® Easy-Digest Goat Milk Infant Formula, along with Bubs Organic® baby food range, cater for all feeding occasions and stages of a child's development during their first 1,000 days of life.

Bubs® products are widely sold in major supermarkets and pharmacies throughout Australia, as well as exported to ten markets across China, Southeast Asia, the Middle East, and USA.

Consumer Website: **bubsaustralia.com**

Investor Centre: **investor.bubsaustralia.com**

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APPENDIX

Summary of Phases for FDA Guidance[1] – Infant Formula Transition Plan

Overview of Phases and timing

Phase	Manufacturer Action Item(s)	Timing Expectation
1	Letter of Intent	By December 5, 2022
2	Plan for Meeting New Infant Formula Requirements	By February 28, 2023
3	Data Demonstrating Sufficient Biological Quality of Protein and Plan to Develop Data Supporting Normal Physical Growth	By June 16, 2023
4	Data Demonstrating Support of Normal Physical Growth	By January 5, 2024 (if seeking exemption from 21 CFR 106.96(b) under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii)) By September 6, 2024 (if intending to comply with 21 CFR 106.96(b) or (c)(2)(i))
5	New Infant Formula Submission	By February 16, 2024 (if seeking exemption from 21 CFR 106.96(b) under 21 CFR 106.96(c)(1), (c)(2)(ii), or (c)(2)(iii)) By October 18, 2024 (if intending to comply with 21 CFR 106.96(b) or (c)(2)(i))

[1]**Link to full document:** *https://www.fda.gov/news-events/press-announcements/fda-pathway-supports-long-term-stability-diversity-safe-and-nutritious-infant-formula-supply-us*