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BUBS AUSTRALIA SECURES U.S. FDA DISCRETION TO IMMEDIATELY IMPORT SIX BUBS INFANT FORMULA PRODUCTS INTO USA TO HELP RELIEVE SHORTAGES

- **USA Food and Drug Administration (FDA) announces** it will exercise **discretion for the immediate import, sale and distribution of all six Bubs® Infant Formula products** into the United States under the agency's recently released Infant Formula Enforcement Discretion Policy.
- Currently working closely with the U.S. Department of Health and Human Services (HHS) to determine the best options for delivering products to the U.S. as quickly as possible.
- Commitment to the Biden Administration to provide **at least 1.25 million tins in the coming weeks and months, equivalent to at least 27.5 million bottles**, across Bubs Supreme™ A2 Beta-Casein Protein, Bubs Organic® Grass Fed, and Bubs® Easy-digest Goat Milk Infant Formula products.
- **Bubs Australia was one of the first to respond (Request Number 001.001)** under the new FDA discretion policy, developed to address the current infant formula shortage and enable increased flexibilities for importation of infant formula.
- FDA discretion marks the completion of a rigorous process reviewing information demonstrating Bubs® Infant Formula meets provisions of safety and adequate nutrition for American families.
- Bubs complete range of infant formula already meets the nutrient requirements of the US Infant Formula Act for an iron fortified infant formula.
- **500,000 tins are ready for immediate export to the United States** with the remaining 750,000 tins production already planned and scheduled for completion in the coming months.
- Leverages established retail distribution footprint and brand awareness of Aussie Bubs™ Toddler Formula already on sale in USA major eCommerce and 'bricks and mortar' retailers.
- Bubs® Infant Formula and Aussie Bubs™ Toddler Formula products are manufactured in Bubs' own **FDA registered production facility**, capable of tripling current 10 million tin annual capacity.
- Bubs supply to existing Australian retailers and export markets to remain unchanged, given ability to increase current and planned production, due to strong control of vertically integrated supply chain and flexibility of our existing wholly owned production facility.

FDA Press Announcement and Enforcement Discretion Notice:

[FDA Efforts to Result in Millions of Additional Bottles of Infant Formula to Further Increase U.S. Supply Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies](#)

Melbourne, 28 May 2022: Bubs Australia (ASX: **BUB**), producer of Bubs Australian made infant formula, advises the USA Food and Drug Administration (FDA) announced on U.S. EST 2pm, 27 May 2022, it has exercised its discretion for Bubs® to import six infant formula products into the United States effective



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immediately, including Bubs Supreme™ A2 Beta-Casein Protein, Bubs Organic® Grass Fed, and Bubs® Easy-digest Goat Milk Infant Formula and Follow-On Formula products.

Responding to and working closely with the Biden Administration and the FDA, Bubs has committed to supply an initial 500,000 tins of infant formula, with a further 750,000 tin commitment over the coming months, which equates to at least 27.5 million feeding bottles of infant formula for American babies.

Bubs Australia's FDA application was in response to the U.S. Government's initiatives to address domestic infant formula supply shortages. Bubs already distributes Aussie Bubs™ Toddler Formula in the USA and has an established retail online and bricks and mortar presence, together with arrangements in place with the USA's top three national wholesale food distributors.

Confirming the green light to import Bubs® Infant Formula into the USA, Founder and CEO, Kristy Carr said: "As an Australian infant nutrition specialist, we welcome the opportunity to support American families in this time of need and provide an immediate source of safe, reliable, and clean range of infant formula.

"Australia and the United States have relied on each other in times of crisis for more than 100 years. This is no different and all credit goes to the U.S. Government for fostering initiatives that allow us to respond and assist. Bubs is uniquely positioned with an existing nationwide sales and distribution footprint, enabling us to stock shelves with existing and prospective retail partners quickly.

"Bubs application was one of the first to be filed with the USA authorities after the FDA released its guidelines for issuing an enforcement discretion notice for the import of certain infant formula products. Bubs' ability to move so quickly in applying for the FDA discretion for importation was a testament to the strength of our agility, innovation, and positive company culture. It was also the result of 18 months of preparation and investment in our USA market expansion strategy, to meet the very stringent quality and safety nutrition requirements for FDA, having first launched a range of high-quality toddler formulas in the USA last year.

"Bubs already has the necessary customer relationships and processes to support the initiative, including supply and distribution logistics, and the appropriate insurances and Aussie Bubs Advisory Board to assist American families. This foundation is a reflection of our long-term commitment to the USA as a strategic priority for the Company, drawing on our 17 years of experience in infant nutrition to ensure that stringent standards and quality control measures were in place to support the launch.

"In addition, we appointed a US Advisory Board comprising leading authorities across clinical research and nutrition, science, and pediatric practitioners aimed at providing a pathway to expand into the infant formula market with appropriate approvals.

"Both Aussie Bubs and Bubs formula ranges are already the recipient of the prestigious USA Clean Label Project Purity Award and the First 1000 Days Promise Clean Label Project Certified, an evidence-based verification process giving parents peace of mind knowing their child is obtaining pure nutrition free from heavy metals, pesticide residues, plasticizers and other chemicals and toxins.

"FDA recognises Australia as having equivalent food standards, and Bubs product integrity is assured through having an integrated supply chain back to the dairy source, including full traceability and tight



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manufacturing controls at our FDA registered facility in Victoria. The facility is currently capable of producing 10 million tins of formula annually and can triple capacity to meet demand," said Kristy Carr.

Dennis Lin, Executive Chairman said: "Bubs had identified USA as a strategic key market two years ago, and our commitment to invest has thankfully coincided with American families' time of need. This allows us to accelerate our strategic vision as well as provide support that goes to the heart of the Bubs DNA."

This announcement was approved by the Board of Directors.

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About Aussie Bubs Incorporated (USA)

<https://aussiebubs.com>

Bubs established a presence in the USA in June 2021, where it distributes and markets Aussie Bubs™ Toddler Formula products. It has established import supply chain and logistics in place, and routinely has shipments cleared via U.S. Customs and Border Protection.

The FDA label-compliant Aussie Bubs™ Toddler Formula products are available online at major e-commerce platforms; over 1,000 brick and mortar stores; direct to consumer via Aussie Bubs website; as well as ranged with the three largest national wholesale distributors in the USA: DPI Specialty Foods, KeHe and UNFI with rapidly increasing retail network.

Aussie Bubs™ Toddler Formula and Bubs® Infant Formula ranges are sourced through Bubs integrated supply chain and manufactured in its FDA registered facility in Victoria, Australia. Aussie Bubs range and existing Bubs formulations meet stringent Clean Label Purity standards with confirmation of the USA certified Clean Label Purity Award.

About Bubs Australia

Founded in 2006 in Sydney, Bubs Australia's vision is to create new generations of happy, healthy bubs and families through its range of premium Australian infant nutrition and goat dairy products, including specialty and nutritional milk powder products for the whole family. Bubs® Goat Milk Infant Formula and Bubs Organic® Grass-fed Cow's Milk Infant Formula, along with organic baby food, cereals, toddler snacks, and Vita Bubs® infant and children's vitamin and mineral supplements, cater for all feeding occasions and stages of development from newborn through to childhood.

Bubs Australia is the leading producer of goat dairy products in Australia with exclusive milk supply back to the farm gate. Bubs is proudly the only infant formula in the world to be based on Australian goat milk.

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

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