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FDA COMMITS TO LONG-TERM FRAMEWORK TO EXPAND INFANT FORMULA OPTIONS

PRESIDENT BIDEN ANNOUNCES NEW OPERATION FLY FORMULA MISSION

- **FDA will develop new framework to allow companies with enforcement discretion approval to have pathway and continue to supply beyond November**
- **Fifth and Sixth air freight shipment confirmed under Operation Fly Formula to transport c. 180,000 tins of Bubs® Infant Formula on 10 and 21 July respectively**

Melbourne, 7 July 2022: Infant nutrition and dairy specialist Bubs Australia (ASX: **BUB**) is pleased to advise the following press releases in the afternoon of 6 July 2022 US Eastern Standard time:

FDA New Framework for Continued and Expanded Access to Infant Formula Options

The U.S. Food and Drug Administration (FDA) has announced that it is developing a new framework for continued, expanded access for U.S. parents and caregivers to those international infant formulas options it has assessed as being safe and nutritious. Under the announcement, the FDA has committed to, amongst others, provide a pathway for companies that import, sell, and/or distribute formula under the FDA's temporary enforcement discretion policy to continue to supply infant formula to the U.S. past November.

The FDA intends to issue further guidance in September on the topic of how companies that have already received temporary enforcement discretion could meet FDA requirements to continue to supply infant formula to the U.S. beyond that time.

Bubs Australia is one of the international manufacturers that has expressed an interest in helping to diversify and strengthen U.S. infant formula supply by continuing to serve the American market permanently.

Bubs Founder and CEO, Kristy Carr said: "We welcome Commissioner Califf's announcement today and look forward to continuing to work with the FDA over the coming months to address any additional steps required to ensure we can supply and market Bubs' safe and nutritious formulas without interruption beyond November and over the longer term."

"Bubs was one of the first international manufacturers to apply to the FDA to import infant formula under the initial enforcement discretion policy. Our long-standing commitment to the U.S. market ensured our ability to provide rapid response at the speed of safety, and satisfy the very stringent quality and safety nutrition requirements of the FDA, having first launched our toddler products in the United States in 2021 with our retail partners," Mrs. Carr said.

Bubs Executive Chair, Dennis Lin, said "Following the recent equity raise, our business is well-resourced to continue to provide safe, reliable and clean nutrition to American families with a transparent supply chain. We welcome the statement from FDA Commissioner Dr Robert Califf today, which provides our business with further clarity to continue to expand our US team and ramp up production plans."



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"With today's announcement by the FDA, we will look to immediately allocate additional production volumes for the U.S. and work with our retail and distribution partners to serve American families beyond November. We will also continue to work with FDA under its guidance to ensure that Bubs can serve the American market permanently," Mr. Lin said.

New Operation Fly Formula

President Biden also announced today that his Administration is sourcing two additional flights, facilitated by the U.S. Department of Health and Human Services (HHS), for Operation Fly Formula to transport additional Bubs Australia infant formula from Australia to Ontario, California and Columbus, Ohio on July 10 and 21 respectively.

These two deliveries will include the equivalent of approximately 180,000 cans of Bubs® Infant Formula including Bubs® Supreme A2 Beta-Casein Infant Formula, Bubs® Supreme A2 Beta-Casein Follow On Formula, Bubs Organic® 365-Day Grass Fed Cow Milk Infant Formula (Stage 1), Bubs Organic® 365-Day Grass Fed Cow Milk Infant Follow On Formula (Stage 2), Bubs® Easy Digest Goat Milk Infant Formula (Stage 1), and Bubs® Easy Digest Goat Milk Follow On Formula (Stage 2).

Mrs. Carr said, "We continue to work closely with the U.S. Government, and we appreciate the latest support from the Biden Administration that ensures our products can be on retailer shelves at first opportunity."

This announcement was authorised by the Board of Directors.



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About Bubs Australia

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 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