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Morinaga Milk obtains FDA GRAS approval for probiotic BB536

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Morinaga Milk Industry, a leading Japanese dairy product company, has announced its proprietary probiotic Morinaga Bifidobacterium longum BB536 has received FDA GRAS (Generally Recognized as Safe) approval relating to its use in term infant formula.



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On December 26, 2019, the U.S. Food and Drug Administration (FDA) issued the company with a GRAS Notice known as ‘no objection letter’, stating it has no questions regarding the safety of the probiotic strain B. longum BB536 when used in infant formula (GRAS Notice No. GRN 000877). The probiotic strain meets the highest standards of safety and regulatory compliance and can be used as an ingredient in powdered infant formula for term infants. After receiving Self-affirmed GRAS in the summer of 2019, the company submitted a notification to the FDA for use in infant formula and received a no objection letter.

Bifidobacterium longum BB536 is a clinically effective, well-established, multifunctional probiotic strain that has a long history of human use. For half a century, B. longum BB536 has been the superior Human-Residential Bifidobacteria (HRB) probiotic strain that provides a consistent beneficial effect in maintaining human health. Already well known as a leading functional probiotic ingredient for application in food and dietary supplements, Morinaga B. longum BB536 is now expanding its application opportunities into the new space, to be specifically used in infant formula.

“This official GRAS notification in infant formula from the U.S. FDA speaks highly the quality, safety and efficacy of our flagship probiotic strain and the solid scientific evidence behind it,” said Ko Shiino, General Manager of Sales and Marketing Department, International Division of Morinaga Milk. “This approval is a regulatory milestone in the United States. The potential implications of this new status are very exciting to be a part of,” he added.

Probiotics have become increasingly popular in infant products as consumers recognition of the need to maintain a healthy intestinal microflora during early life for lifelong well-being is getting stronger. Initial neonatal gut microbial colonization

represents a crucial window of opportunity for shaping a healthy gastrointestinal tract and driving the maturation of immune system. Bifidobacteria are among the first microbes to colonise the infants' gut and play vital roles in regulating immunological and physiological functions. Perturbation of early life gut microbial colonization, particularly delayed bifidobacterial colonization, has been linked with the development of allergies, eczema, and other microbiome-related disease pathologies.

"An infant's gut microbiota is adversely affected by a variety of factors such as the delivery mode, type of feeding, or antibiotic use," said Dr. Xiao, General Manager of Next Generation Science Institute of Morinaga Milk. "Therefore, it is of utmost importance to establish a bifidobacteria-dominant gut microbiota, and the clinically proven probiotic strain B. longum BB536 is one strain that can aid infants in this process," he noted.

Morinaga B. longum BB536 was the first Human-Residential Bifidobacteria (HRB) strain to receive the FDA GRAS notification for use in conventional foods and beverages (GRAS Notice No. GRN 000268) and has been incorporated in various products worldwide for more than 50 years. Affirmation of this newest status adds value to the company's proprietary probiotic strain, diversifying its application options available in the infant category.