



Morinaga Milk Industry Co., Ltd., Receives U.S. FDA Letters of No Objection for its Proprietary Probiotic

U.S. FDA Non-Objection to GRAS Notifications Regarding the Proprietary Probiotic Strain Morinaga Bifidobacterium breve M-16V for Food Applications and Infant Formulas

TOKYO (NOVEMBER 5, 2013) — Morinaga Milk Industry Co., Ltd.(TOKYO:2264), the second largest dairy product company in Japan, today announced that the U.S. Food and Drug Administration ("FDA") has issued Generally Recognized as Safe (GRAS) Letters of No Objection for Morinaga's proprietary probiotic strain, *Bifidobacterium breve* M-16V for food applications and infant formulas.

The GRAS process is an FDA-recognized pathway that permits companies to have GRAS reviews carried out by independent panels of scientists, followed by GRAS determinations if an ingredient meets the FDA's criteria for safety. To ensure even greater confidence in its ingredients, Morinaga has submitted its safety dossiers to the U.S. FDA for review, which has resulted in these two Letters of No Objection.

On September 27, the U.S. FDA issued "letters of no objection" in response to Morinaga's safety submissions for *Bifidobacterium breve* M-16V for food uses (GRAS Notice No. GRN 000453) and for use in infant formulas (GRAS Notice No. GRN 000454).

Bifidobacterium breve M-16V, Morinaga's second flagship probiotic strain, will be officially introduced at Supply Side West trade show in Las Vegas, Nevada on November 14 and 15, 2013.

In 2009, Morinaga achieved GRAS status for its first flagship probiotic ingredient, *Bifidobacterium longum* BB536 (GRAS Notice No. GRN 000268), one of the best-selling probiotics in Japan.

"A GRAS determination for an ingredient intended for use in infant formula requires the utmost care that assurance of safety for this sensitive sub-population be completed using the most current and rigorous of scientific and regulatory standards," said Claire Kruger, Ph.D., D.A.B.T., president of Irvine, CA-based Spherix Consulting, one of the expert panel members involved in the self-affirmed GRAS determination for *Bifidobacterium breve* M-16V in 2012.

"The safety of *Bifidobacterium breve* M-16V was confirmed by a thorough Expert Panel review of this probiotic, including an evaluation of all data against the safety standards enumerated by the Food and Agriculture Organization of the United Nations' World Health Organization (FAO/WHO) guidelines for the evaluation of microbes for probiotic use in foods," Dr. Kruger added.

Bifidobacterium breve M-16V is a strain of *Bifidobacterium* which occurs naturally in the gut microbiota of healthy infants and adults, along with Morinaga's flagship probiotic strain *Bifidobacterium longum* BB536, one of the most thoroughly researched probiotic strains in the world. Thirty-four scientific papers on M-16V have been published that support the use of this probiotic in maintaining healthy condition for human.

“M-16V has been recognized for its safety and effectiveness, especially for low-birth-weight infants to help promote healthy growth, and is used in approximately 100 hospitals in Japan for low-birth-weight infants in Neonatal Intensive Care Units (NICU). Because of its effectiveness, some doctors cannot stop using it in the hospitals,” stated Michio Ikeda, General Manager of Morinaga’s International Department. “We will accelerate our activities to document its safety and contribution to infant health around the world.”

The characteristics of the M-16V probiotic are:

- Human residential bacteria (being predominant bifidobacterial species in the intestinal microbiota of infants)
- High stability due to Morinaga’s unique culturing technology
- Supported by 34 scientific studies including clinical studies on low-birth-weight infants
- Manufactured in a HACCP (Hazard Analysis and Critical Control Points) compliance-certified facility
- Used in the NICU of more than 100 hospitals in Japan
- Safety confirmed by genome sequence analysis, antibiotic resistance studies, toxicology tests and clinical studies

Morinaga representatives will be happy to discuss the benefits and uses of Morinaga M-16V and other probiotics for food and supplement applications at Supply Side West in Las Vegas, Nevada on November 14 and 15, 2013. Please visit Morinaga Booth No. 23073 for more information.

About Morinaga

Morinaga Milk Industry Co., Ltd. is the second largest dairy product company in Japan, employing 3,122 people. Founded in 1917, Morinaga exhibit excellence in the field of technology and sell not only dairy products but also the beneficial functional ingredients isolated from milk components. Morinaga has been exporting its products and technology to around 30 overseas countries for more than 30 years.

IF YOU WOULD LIKE MORE INFORMATION ABOUT MORINAGA M-16V AND OTHER PROBIOTICS, OR TO SCHEDULE AN INTERVIEW, PLEASE SEND AN E-MAIL TO: INTERNTL@MORINAGAMILK.CO.JP

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