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PRESS RELEASE

FDA confirms Arla Foods Ingredients' whey protein hydrolysates can be used in infant formula

Arla Foods Ingredients has secured US Food & Drug Administration approval for the use of whey protein hydrolysates that support allergy management and gut comfort in infant formula.

The FDA agreed that four ingredients in the company's Peptigen® and Lacprodan® ranges meet the definition of peptones in the US Code of Federal Regulations. As such, they are permitted for use in early life nutrition.

Anders Steen Jørgensen, Head of Arla Foods Ingredients' Pediatric Business Unit, said: "We have over 30 years' experience of developing and producing safe, high-quality whey protein hydrolysates for the infant formula market at our state-of-the-art manufacturing facilities. Our strategy is to ensure these scientifically backed ingredients are available all over the world. We are delighted that US infant formula manufacturers can now use four of our hydrolysates in infant nutrition products targeting cow's milk allergy management or reduction of gut discomfort."

It is estimated that 2-3% of infants in the US now suffer from cow's milk allergy.¹ In most cases where breastfeeding is not possible, hydrolyzed formulas backed by clinical proof of efficacy are recommended for them.

The four ingredients now permitted by the FDA for use in early life nutrition products are:

- Peptigen® IF-3032, an extensively hydrolyzed whey protein recommended for use in allergy management nutrition solutions. Multiple clinical studies support its suitability for infants with cow's milk allergies.²
- Peptigen® IF-3080, which is also suitable for allergy management nutrition solutions, and secured safety and suitability approval from EFSA for use in infant formula and follow-on milk in the EU in 2023.
- Peptigen® IF-3085, a partially hydrolyzed protein, which can be suitable in products for infants at high risk of developing milk allergies.
- Lacprodan® IF-3070, which is designed to support the reduction of gastrointestinal discomfort.

Anders Steen Jørgensen added: "We invest heavily in preclinical and clinical trials to provide scientific evidence for our ingredients' benefits. Our whey protein hydrolysates have been shown to support the safe growth of formula-fed infants who are unable to tolerate traditional milk-based formulas."

Arla Foods Ingredients has received approval for Lacprodan® IF-3070 and Lacprodan® DI-3072 for the Chinese formula market, and additional hydrolysate products are going through the country's approval process.

For more information contact:

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About Arla Foods Ingredients

Arla Foods Ingredients is a global leader in improving premium nutrition. Together with our customers, research partners, suppliers, NGOs and others, we discover and deliver documented ingredients and products that can advance lifelong nutrition for the benefit of consumers around the world.

We serve leading global brands in early life nutrition, medical nutrition, sports nutrition, health foods, and other foods and beverages.

Five reasons to choose us:

- We're passionate about improving nutrition
- We innovate by connecting the best
- We master both discovery and delivery
- We build strong, long-lasting partnerships
- We are committed to sustainability

Headquartered in Denmark, Arla Foods Ingredients is a 100% owned subsidiary of Arla Foods.

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¹ Ward C.E., Greenhawt M.J. Treatment of allergic reactions and quality of life among caregivers of food-allergic children. *Ann Allergy Asthma Immunol Off Publ Am Coll Allergy Asthma Immunol* (2015)

² Halken, S., Host, A., Hansen, L. G. & Østerballe, O. Safety of a new, ultrafiltrated whey hydrolysate formula in children with cow milk allergy: a clinical investigation. *Pediatric Allergy and Immunology* 4, 53–59 (1993)