

Cataya Received FDA GRAS Status for Its First Human Milk Oligosaccharide Product, 2'-Fucosyllactose

"No questions" letter from US Food and Drug Administration signals support for the safety and suitability of Cataya's 2'-Fucosyllactose for use in infant formula and various conventional foods

Shanghai, China Jul 6, 2025 ([IssueWire.com](https://www.issuewire.com)) - Cataya Bio (Shanghai) Co., Ltd. ("Cataya"), a leading developer and manufacturer of sustainable ingredients powered by advanced synthetic biology platforms, today announced that it has received a "No Questions" letter from the U.S. Food and Drug Administration (FDA) regarding its first human milk oligosaccharide (HMO) product, 2'-Fucosyllactose (2'-FL). The letter affirms the FDA's acceptance of Cataya's conclusion that its 2'-FL ingredient is safe and suitable to be used in non-exempt infant formula and various conventional foods.

HMOs are the third most abundant solid component in human breast milk, after lactose and lipids, but are rare in cow's milk. Among over 200 types of HMOs, 2'-FL is the most abundant, making up to 30% of total HMOs. 2'-FL supports infant growth, cognitive development, immune function, and digestive health. Already widely used in infant formulas, 2'-FL is driving rapid growth in the global HMO market.

"Receiving the FDA's No Questions letter for GRAS status is a significant milestone that underscores Cataya's commitment to safety, quality, and innovation," stated Dr. Lishan Zhao, CEO of Cataya. "We are dedicated to delivering safe, science-backed solutions for infant formula, food manufacturers, and infants. Regulatory approvals for 2'-FL are progressing in multiple regions, and we are actively expanding our HMO product pipeline. We believe Cataya is well positioned to become a global leader in the supply of HMOs."

About Cataya

Founded in 2021, Cataya Bio (Shanghai) Co., Ltd. is a next-generation biotech company dedicated to rapidly developing and manufacturing high-value ingredients at low cost and with a sustainable footprint. Leveraging advanced synthetic biology platforms and cutting-edge biomanufacturing capabilities, Cataya enables rapid, efficient, and scalable production of ingredients for the personal care, food & nutrition, and pharmaceutical industries.

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