

# Cataya's 6'-Sialyllactose (6'-SL) obtains FDA GRAS status, opening the U.S. Market

**Shanghai, China Mar 30, 2026** ([IssueWire.com](https://www.issuewire.com)) - Cataya Bio (Shanghai) Co., Ltd. ("Cataya") officially announces that its HMO product, 6'-Sialyllactose (6'-SL), has successfully obtained U.S. FDA GRAS (Generally Recognized as Safe) status (GRN1275). The FDA has issued a "No Questions" letter, opening access to the U.S. market.

## A Milestone in Safety and Global Standards

A "No Questions" letter from the FDA is the highest level of safety affirmation from the FDA and follows a rigorous review by the FDA of Cataya's product, technology and quality management. The review included the steps taken by Cataya to avoid cereulide contamination. Unlike many similar products on the market, Cataya's 6'-SL is produced through precision fermentation of a safe QPS microorganism. The issuance of the letter fully opens the U.S. market, including the infant nutrition market, for Cataya's 6'-SL product.

## Benefiting Infant Health and Beyond

6'-SL is the most abundant sialylated Human Milk Oligosaccharide (HMO) in human breast milk. Addition of 6'-SL to infant formula brings infant formula closer to breast milk. 6'-SL plays multiple roles in the health and development of infants, for example supporting healthy brain development, regulating the infant gut microbiota, and beneficially modulating the infant immune system. 6'-SL can also benefit the health and development of children and adults, including elderly and athletes.

## Strategic Global Expansion

This achievement is a direct result of Cataya's deep commitment to quality and safety in the field of synthetic biology and continuous technical innovation. Following successfully obtaining FDA GRAS status for its 2'-Fucosyllactose (2'-FL) product, the issuance of "No questions" 6'-SL further strengthens market access for the company's comprehensive HMO product portfolio.

Dr. Lishan Zhao, CEO of Cataya, stated that obtaining US FDA GRAS status is an important step in the company's global strategy. Moving forward, the company will continue to expand market access for its portfolio of nutritional actives, especially in the infant and elderly markets.

## Leading the Industry Forward

Founded in 2021, Cataya Bio (Shanghai) Co., Ltd. develops and manufactures high-value nutritional and personal-care ingredients using cutting-edge synthetic biology and sustainable large-scale bioproduction. Cataya combines world-class, synthetic biology research capabilities with state-of-the-art, fully integrated manufacturing capabilities. Cataya's mission is to enable efficient and environmentally responsible manufacturing of product solutions which deliver real benefits for consumers and drive growth and margins for partners in food, nutrition and personal care.

For more information, visit [www.cataya.com](https://www.cataya.com).

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