Formo receives first FDA “no questions” letter for Enhanced Casein made through precision fermentation

Regulatory milestone advances Formo's Enhanced Casein as U.S. manufacturers seek alternatives to traditional protein sources and greater functionality in next-generation food and beverage products.

FRANKFURT / DOVER, Delaware, October 28, 2026 – Formo today announced that its Enhanced Casein has become the first precision fermentation-derived casein to receive a “no questions” letter from the U.S. Food and Drug Administration (FDA), following the agency’s review of its Generally Recognized as Safe (GRAS) notification. The milestone confirms that FDA has no questions regarding the safety conclusion for the ingredient under its specified conditions of use.

FDA’s review covered the full scientific dossier: identity and composition, the manufacturing process, allergenicity, toxicology and dietary exposure. The Notice, filed in December 2025, covers use in cheese analog applications at up to 25 grams per 100 grams. It was prepared and filed jointly with Those Vegan Cowboys under a research collaboration that successfully concluded in 2025. Both companies now develop and sell their products independently. Building on its existing safety dossier, Formo plans to submit an additional GRAS Notice to support expanded use of its Enhanced Casein across a broader range of food and nutrition applications.

U.S. demand for high-protein products is growing, while the whey ingredients many manufacturers rely on have become far more costly and difficult to source. USDA market reports put whey protein isolate above $13 per pound and whey protein concentrate around $10, both more than three times their early-2023 prices. For manufacturers, the challenge is finding protein sources that can support both dependable supply and demanding formulations. Formo’s Enhanced Casein offers a new high-quality protein option, with differentiated functionality for product development.

“This is an important milestone for Formo and a significant step in building confidence in precision-fermented proteins,” said Raffael Wohlgensinger, Founder and CEO of Formo. “Food and nutrition manufacturers need more than new sources of protein. They need ingredients that deliver consistent quality and the functionality to overcome real formulation challenges. That’s what we’re building with Enhanced Casein: a protein that opens new possibilities for product innovation and enables applications that have traditionally been difficult to formulate.”

Protein designed to perform

Formo produces Enhanced Casein through commercial-scale precision fermentation, creating a well-characterized protein with differentiated functional properties. Produced to a consistent specification, batch after batch, the ingredient offers manufacturers a new source of high-quality protein independent of traditional dairy farming.

Protein demand is changing not just in volume, but in what manufacturers need protein to do. Formulators developing high-protein foods, performance nutrition products and next-generation dairy applications need proteins with consistent composition, reliable functionality and dependable supply. Yet formats such as high-protein bars and shelf-stable ready-to-drink beverages remain challenging to formulate, as higher protein levels can compromise taste, texture, solubility and heat stability. Formo's Enhanced Casein is clean by design to help overcome these challenges, offering differentiated functionality without lactose, antibiotics or hormones.

Formo's Enhanced Casein offers differentiated functionality across a range of beverage applications. In clear, acidic beverages, it maintains solubility at low pH (3–4) with protein concentrations up to 6% in tested formulations. Its strong foaming capacity and stability make it well suited for barista applications, including high-protein cold foams, while its lower viscosity at high protein concentrations supports the development of ready-to-drink beverages without compromising mouthfeel. Together, these properties give manufacturers greater flexibility to develop innovative, protein-rich products.

Commercial readiness

Formo supplies the ingredient to U.S. food and nutrition companies through its U.S. subsidiary, Formo Foods Inc., and a network of commercial partners. For large food companies, a completed FDA review is typically the step that moves a new ingredient from the innovation bench into procurement.

“Protein is driving growth across the U.S. food and nutrition market, but traditional supply is struggling to keep pace,” said Wohlgensinger. “Clear protein beverages are a good example. Manufacturers have relied heavily on whey protein isolate, which has become increasingly expensive and difficult to source. Our Enhanced Casein offers a new option that combines a compelling nutritional profile with the functionality to expand what's possible in high-protein formulations. We're building supply alongside customers ready to bring those innovations to market.”

Enhanced Casein in action

At SupplySide Global in Las Vegas, October 28–30, Formo will showcase the functionality of its Enhanced Casein through two demonstrations: a clear protein beverage and a high-protein cold foam for coffee. Attendees are invited to visit booth #2177 to experience both applications and meet the Formo team. For those not attending, contact sales@formo.bio to learn more about Enhanced Casein and explore opportunities for collaboration.

About Formo

Formo is a specialized protein ingredient company headquartered in Germany, building commercial-scale production of recombinant casein through precision fermentation for food and nutrition companies.

Its recombinant αS1-casein is the first recombinant casein to receive an FDA “no questions” letter. In the U.S., Formo operates through Formo Foods Inc. More at www.formo.bio

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Note to editors

A “no questions” letter is FDA’s response at the close of a GRAS Notice review. It is not a product approval. The NQL applies to the intended conditions of use in the Notice: cheese analog applications at up to 25 g per 100 g, excluding infant formula and products under USDA jurisdiction. Formo’s Enhanced Casein is the recombinant αS1-casein notified under GRN 1312. The Notice and FDA’s response letter will be public in the FDA GRAS Notice Inventory. Like the casein in cow’s milk, Formo’s Enhanced Casein is a milk allergen and is not suitable for people with a milk allergy.

Market data: USDA AMS Dairy Market News, Whey Protein Concentrate - Central and West U.S., Report 6 (February 9, 2023) and Report 43 (October 22, 2026).