



Tianli Liu  
CABIO Biotech (Wuhan) Co., Ltd.  
Wuhan Pharmacy Park, Jiangxia Avenue  
Jiangxia Economic Development Zone  
Wuhan, CHINA

Re: GRAS Notice No. GRN 001281

Dear Tianli Liu:

The Food and Drug Administration (FDA, we) is responding to GRN 001281. We received the notice that you submitted on behalf of CABIO Biotech (Wuhan) Co., Ltd. (CABIO) on May 22, 2025, and filed it on August 11, 2025. CABIO submitted amendments to the notice on January 30, 2026, April 1, 2026, and April 2, 2026.<sup>1</sup>

The subject of the notice is 2'-fucosyllactose (2'-FL) for use as an ingredient in cow milk- and soy-based, non-exempt infant formula for term infants and formula for young children (>12 months) at a maximum level of 2.4 g/L, and in other food categories at levels specified in the notice. CABIO states that 2'-FL is not intended for use in products under the U.S. Department of Agriculture's jurisdiction and in foods for which standards of identity do not permit its addition. The notice informs us of CABIO's view that these uses of 2'-FL are GRAS through scientific procedures.

CABIO recently refused FDA inspection of its facilities in China, leading FDA to include all products from CABIO intended for the U.S. market on Import Alert (IA) 99-32 "Detention Without Physical Examination of Human and Animal Food Products from Foreign Establishments Refusing FDA Inspection." FDA often conducts establishment inspections of foreign manufacturers who produce FDA-regulated articles intended for sale in the U.S. Access to these facilities is a critical aspect of protecting the health and safety of U.S. citizens from unsafe products of foreign origin. In light of CABIO's refusal and the inclusion of CABIO's products on IA 99-32, we have questions about the safety of 2'-FL produced by CABIO that is the subject of this notice.<sup>2</sup>

## Conclusions

Based on CABIO's recent addition to IA 99-32 for all products intended for the U.S.

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<sup>1</sup> Based on CABIO's responses and other information available to us, we determined that the subject of this notice was not yet used in infant formula in the U.S.

<sup>2</sup> This response is limited to 2'-FL as manufactured by CABIO. We are not questioning the safety of 2'-FL as reviewed by FDA in other GRNs.

market, we have questions regarding the safety of any ingredients manufactured by CABIO; therefore, we do not agree that there is a sufficient basis for a conclusion of GRAS status for the intended use of 2'-FL manufactured by CABIO.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001281 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**SUSAN J.**

**CARLSON -S**

Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Pre-Market Additive Safety

Office of Food Chemical Safety, Dietary

Supplements, and Innovation

Human Foods Program

Digitally signed by SUSAN J.  
CARLSON -S

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