



February 6, 2025

Alan B. Richards, Ph.D.
Agent for Nagase Viita Co., Ltd. Vanguard
Regulatory Services, Inc.
1311 Iris Circle
Broomfield, Colorado 80020

RE: Docket FDA-2024-P-3820

Dear Dr. Richards:

This letter is in response to the citizen petition (FDA-2024-P-3820) received on August 10, 2024, in which you requested, on behalf of Nagase Viita Co., Ltd. that the Food and Drug Administration (FDA) amend 21 CFR § 101.9(c)(6)(i) by adding Isomaltodextrin (Fibryxa®) to the existing list of isolated or synthetic non-digestible carbohydrates determined by FDA to have physiological effects that are beneficial to human health.

In accordance with Title 21 of *the Code of Federal Regulations*, section 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and the limited availability of resources. When we complete our review of your petition, we will notify you of our decision.

Please let us know if you have any questions.

Sincerely,

Claudine Kavanaugh, PhD, MPH, RD
Director
Office of Nutrition
and Food Labeling
Nutrition Center of Excellence