



September 29, 2022

Re: Docket No. FDA-2020-P-0863

Thomas B. Shea, Ph.D.
Head of Scientific Advisory Board
Sevo Nutraceuticals, Inc.
800 Main Street
Holden, MA 01520

Dear Dr. Shea:

FDA is requesting a 1-year extension in order to complete our review of the qualified health claim petition submitted by Sevo Nutraceuticals, Inc., regarding an evidence-based qualified health claim that a nutraceutical formulation (brand name Perceptiv) can reduce the risk of Alzheimer's Disease and cognitive decline during aging.

We are continuing to work on responding to your petition in addition to our other priority work. As you are aware, we have limited resources, and many of them have been devoted to responding to the nationwide infant formula shortage in recent months. With this 1-year extension, we would inform you of our decision by September 29, 2023.

Unless an extension for reaching a decision about the petition is mutually agreed upon between FDA and the petitioner, the petition would be deemed denied.

Please reply to this letter (email is acceptable) and let me know if Sevo Nutraceuticals, Inc. agrees to the 1-year extension we are requesting.

Please feel free to call me at 240-402-2082 if you have any questions or would like to discuss this matter further. Thank you for your consideration.

Sincerely,

Mark A. Kantor, Ph.D.
Nutrition Assessment and Evaluation Team
Office of Nutrition and Food Labeling