



FEB 20 2020

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

RE: Petition for a qualified health claim entitled "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" (Docket No. FDA-2020-P-0863)

Dear Dr. Shea:

This letter is in reference to the qualified health claim petition received by the Food and Drug Administration (FDA or we) on January 6, 2020, that you submitted on behalf of Sevo Nutraceuticals, Inc., pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 343(r)(4) and 343(r)(5)(D)) and in accordance with FDA's qualified health claim guidance (July, 2003).

The petition requests a qualified health claim for the relationship between consumption of a nutraceutical formulation and the reduction in risk of Alzheimer's disease and cognitive decline during aging. We have completed our initial review of the petition and we will now review the petition as petition for a qualified health claim in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative (<https://www.fda.gov/food/food-labeling-nutrition/consumer-health-information-better-nutrition-initiative-task-force-final-report>). In accordance with the interim procedures set forth in the aforementioned Task Force Final Report, today, we are filing the petition for a qualified health claim for the consumption of a nutraceutical formulation and the reduction in risk of Alzheimer's disease and cognitive decline during aging.

The petition is posted at <http://www.regulations.gov> and we are requesting comment on it for 60 days. Interested persons may submit comments until April 20, 2020. The Docket number for the petition is FDA-2020-P-0863. Within 270 days of the receipt of the petition, we will notify


**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

Page 2 – Thomas B. Shea, Ph.D.

you of our final decision regarding the requested qualified health claim. We have calculated this date to be October 2, 2020.

If you have any questions, please contact Mark A. Kantor in the Nutrition Programs Staff at 240-402-2082.

Sincerely,

A handwritten signature in blue ink, appearing to read "Claudine Kavanaugh", with a long, sweeping flourish extending to the right.

Claudine Kavanaugh, PhD, MPH, RD  
Director  
Office of Nutrition  
and Food Labeling  
Center for Food Safety  
and Applied Nutrition