JAN 2 1 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"

Dear Dr. Shea:

This letter acknowledges receipt on January 6, 2020 by the Food and Drug Administration
(FDA) of the petition you submitted, on behalf of Sevo Nutraceuticals, Inc., pursuant to
Section 403(r)(4) and to Section 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 guidance on the
procedures for the submission of qualified health claim petitions. 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.

The petition is undergoing initial FDA review. In accordance with the aforementioned
"Guidance for Industry: FDA's Implementation of Qualified Health Claims," (May 2006)
(https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-
industry-fdas-implementation-qualified-health-claims), within 45 days of receipt of your
petition, you will be notified of FDA's decision to either file the petition for comprehensive
review, or to deny the petition. A denial may either be by FDA action within the initial 45-day
period, which ends on February 20, 2020, or by a lack of action by FDA within the initial 45-
day period, in which case the petition shall be deemed to be denied unless an extension is
mutually agreed upon by FDA and the petitioner.

Please feel free to contact me at 240-402-2082 if you have questions concerning this petition.

Sincerely,

Mark A. Kantor, Ph.D.
Nutrition Programs Staff
Office of Nutrition and Food Labeling
Center for Food Safety
and Applied Nutrition