DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Orrin G. Hatch
United States Senate
Washington, D.C. 20510-4402

DEC 16 2016

Dear Senator Hatch:

Thank you for your letter of October 25, 2016, regarding the September 7, 2016 *Federal Register* Notice FDA-2016-N-2523, Request for Comment on the Status of Vinpocetine. Specifically, you urged the Food and Drug Administration (FDA or the Agency) to withdraw the Notice and conduct cost-benefit analyses when considering the merits of withdrawing dietary supplements from the market when safety is not the predicating reason for withdrawal.

Please note that FDA has not taken any action or reached any final conclusions regarding vinpocetine at this time. In the Notice, we presented our tentative conclusions that (1) vinpocetine does not appear to fit any of the categories of "dietary ingredient" established by the Dietary Supplement Health and Education Act and (2) it appears that vinpocetine was authorized for investigation as a new drug in clinical trials before it was ever used as a food or dietary supplement, and also that substantial clinical trials of vinpocetine for use as a drug have been instituted and their existence has been made public. Because we recognize that there may be information of which we are not aware that is relevant to these questions, the purpose of our Notice was to request information from industry and other stakeholders that can help us reach a fully-informed conclusion.

As you observed, FDA received several new dietary ingredient (NDI) notifications for vinpocetine between 1997 and 1999. Although we do not have the authority to approve the marketing of NDIs or dietary supplements and we made no affirmative conclusion at that time as to the regulatory status of vinpocetine or products containing it, you are correct that the Agency did not object to any of those notifications. Due to staff turnover since the 1990s when the notifications for vinpocetine were reviewed, we cannot explain today why FDA did not object then. However, our NDI notification review process has evolved and become more thorough over time. Based on the information that we have now, it appears that we would object to an NDI notification for vinpocetine if one were to come before us for the first time. Again, we realize that we may not have all of the relevant information before us, and this is why we have issued the *Federal Register* notice requesting information. As of November 14, 2016, 836 comments had been submitted to the public docket, and we will carefully consider them all.

With regard to your question as to whether the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) reviewed the economic impact of the Federal Register notice under Executive Order 12866, we did not submit the notice to OIRA for review because it simply solicits comments and information. The notice takes no substantive action,

reaches no final conclusions about vinpocetine, has no legal or economic effect, and is not expected to result in the promulgation of a final rule or regulation.

We are aware that, by not objecting to the NDI notifications, FDA allowed the development of a market for dietary supplements containing vinpocetine, and we are cognizant of the fact that numerous firms did their best to comply with the law in reliance on our apparent regulatory posture. We assure you that FDA will be mindful of the need to treat responsible companies fairly as we move forward and that we will comply with all relevant statutes and regulations as we determine what next steps are appropriate.

Thank you, again, for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Dayle Cristinzio
Associate Commissioner
of Legislation