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October 25, 2016

Dr. Robert Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf,

The Food and Drug Administration (FDA) issued the Federal Register Notice FDA-2016-N-2523, Request for Comment on the Status of Vinpocetine, on September 7, 2016. This notice states that the FDA has altered its conclusion that vinpocetine is a dietary ingredient, and that it should no longer be a covered substance under the Food, Drug, & Cosmetics Act. As cosponsored by nearly two-thirds of Congress, Section 4 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) provides pathways for withdrawing dietary ingredients based on safety concerns. Citing no risk of illness or hazard to public health, this Notice creates uncertainty in the market as to what steps manufacturers can take to sell safe products.

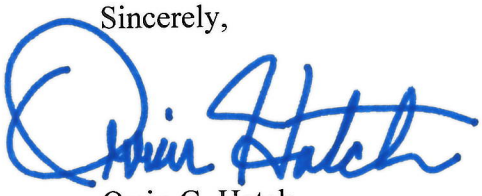
In order to ensure consumer safety, the FDA has the authority under DSHEA to conduct product reviews when safety concerns arise. In 1997, 1998, and three times in 1999, the FDA reviewed New Dietary Ingredient notifications for vinpocetine, each time pulling the product for 75 days and conducting safety and regulatory checks. Each evaluation was an opportunity to raise concerns about whether vinpocetine was a valid dietary ingredient, yet the FDA did not object to the product during any of the five reviews, allowing it to proceed to the market each time.

This Notice also raises questions as to whether the Office of Management and Budget did a full review of the economic impact of this proposal. According to Executive Order 12866, the Office of Information and Regulatory Affairs of the Office of Management and Budget should follow a transparent process when a federal agency makes a determination that is significant. Vinpocetine has a large footprint in the dietary supplement market and serves as a component in many common products. As this is the first time that FDA has attempted to pull a product for a definitional reason instead of a public health concern, a complete and thorough economic impact analysis should be completed.

I have great trust in the experts of the FDA, as do the American people. By removing a product from market without safety concerns, FDA would be taking a precedential step that could shake the confidence that manufacturers maintain in the FDA process. Given that FDA has had five previous opportunities to make this change, yet returned the product to market, the agency signaled that the product could be sold in the U.S. As such, I urge you to withdraw this Notice

and conduct cost-benefit analyses when considering the merits of withdrawing dietary and nutritional supplement products when safety is not the predicating reason for withdrawal.

Sincerely,



Orrin G. Hatch
United States Senator