

# United States Senate

SPECIAL COMMITTEE ON AGING  
WASHINGTON, DC 20510-6400  
(202) 224-5364

October 6, 2015

The Honorable Stephen Ostroff, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Ostroff,

It has come to my attention that two synthetic or semisynthetic substances, “vinpocetine” and “picamilon,” are currently being sold as ingredients in dietary supplements in the United States.<sup>1</sup> These ingredients, which are widely available across the United States, are classified as prescription drugs in other countries.<sup>2</sup>

A recent report reviewing products containing vinpocetine and picamilon revealed that products on U.S. shelves routinely contain prescription-level doses of these ingredients.<sup>3</sup> As you know, the law governing dietary supplements prohibits the inclusion of synthesized ingredients like those found in prescription drugs.<sup>4</sup> Because these ingredients are being sold as dietary supplements and not prescription drugs they have not undergone the same level of scrutiny to understand any potential side effects or drug interactions. In the interest of public safety, I request that FDA take all appropriate action to immediately cease the sale of dietary supplements containing these ingredients until it can be determined if they are appropriate for consumption as dietary supplements.

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<sup>1</sup> Avula, B., Chittiboyina, A. G., Sagi, S., Wang, Y.-H., Wang, M., Khan, I. A., and Cohen, P. A. *Identification and quantification of vinpocetine and picamilon in dietary supplements sold in the United States* (October 2015) (online at: <http://onlinelibrary.wiley.com/doi/10.1002/dta.1853/full>); *Common Memory Supplements Spiked With Vinpocetine, a Prescription Drug*, Consumer Reports (October 2015) (online at: <http://www.consumerreports.org/cro/health/Memory-Supplements-Spiked-With-Vinpocetine>).

<sup>2</sup> *Russian Drugs Pass as Supplements in U.S. - Two pharmaceutical-grade drugs are being marketed as brain-boosting supplements*, MedPage Today (October 2015) (online at: <http://www.medpagetoday.com/clinical-context/MultipleSclerosis/53840>).

<sup>3</sup> Avula, B., Chittiboyina, A. G., Sagi, S., Wang, Y.-H., Wang, M., Khan, I. A., and Cohen, P. A. *Identification and quantification of vinpocetine and picamilon in dietary supplements sold in the United States* (October 2015) (online at: <http://onlinelibrary.wiley.com/doi/10.1002/dta.1853/full>).

<sup>4</sup> Dietary Supplement Health and Education Act of 1994, Public Law 103-417.

Additionally, I understand that a manufacturer of products containing vinpocetine submitted a New Dietary Ingredient notification to the FDA in 1997.<sup>5</sup> This notification, which is required for all dietary supplement ingredients not on the market before 1994, seems to have met little scrutiny from FDA as to the product's allegedly synthesized origins, as it has been on U.S. shelves for several years.<sup>6</sup> To assist my understanding of the FDA's role in allowing ingredients like vinpocetine, that are classified as prescription drugs in other countries, to be labeled dietary supplements in the United States, I request that you provide copies of any New Dietary Ingredient materials submitted to FDA by manufacturers of supplements containing vinpocetine or picamilon, as well as any adverse event reports associated with either ingredient. I also ask that you provide my staff with a briefing related to these ingredients and any action that FDA plans to take related to them.

Ensuring the health and safety of America's seniors is one of the most important duties of the Senate Special Committee on Aging. As such, I greatly appreciate your assistance and cooperation with this matter. I request that you provide the requested documents as soon as possible, but no later than October 12, 2015. To ensure that all documents are produced in accordance with this request, please see the attached production instructions. Please contact Caitlin Warner of the Aging Committee staff at (202) 224-0185 with any questions. Please send any official correspondence related to this request to [Caitlin\\_Warner@aging.senate.gov](mailto:Caitlin_Warner@aging.senate.gov) and [Matt\\_Lawrence@aging.senate.gov](mailto:Matt_Lawrence@aging.senate.gov).

Sincerely,



Claire McCaskill

Ranking Member

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<sup>5</sup> *Common Memory Supplements Spiked With Vinpocetine, a Prescription Drug*, Consumer Reports (October 2015) (online at: <http://www.consumerreports.org/cro/health/Memory-Supplements-Spiked-With-Vinpocetine>); *Russian Drugs Pass as Supplements in U.S. - Two pharmaceutical-grade drugs are being marketed as brain-boosting supplements*, MedPage Today (October 2015) (online at: <http://www.medpagetoday.com/clinical-context/MultipleSclerosis/53840>).

<sup>6</sup> *Russian Drugs Pass as Supplements in U.S. - Two pharmaceutical-grade drugs are being marketed as brain-boosting supplements*, MedPage Today (October 2015) (online at: <http://www.medpagetoday.com/clinical-context/MultipleSclerosis/53840>).