

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

May 17, 2013

Mr. Anthony N. Truesdale
Chief Executive Officer
The Vitamin Shoppe
2101 91st Street
North Bergen, N.J. 07047

Dear Mr. Truesdale:

Pursuant to Rules X and XI of the United States House of Representatives, the Committee on Energy and Commerce is examining the safety of an amphetamine derivative called dimethylamylamine (DMAA) as well as the marketing and distribution of products containing this stimulant.

On April 24, 2012, the U.S. Food and Drug Administration (FDA) sent Warning Letters to 10 companies who used DMAA in products being marketed as dietary supplements. The Warning Letters noted that DMAA raises blood pressure and could precipitate cardiovascular events, including heart attacks. All but one of these companies – USPlabs, LLC (USPlabs) – agreed to stop using DMAA in their products. USPlabs has since phased out products containing DMAA from its production, though remaining supply continues to be sold by certain retailers.

In February 2013, the *New York Times* published an article highlighting the fact that General Nutrition Centers, Inc. (GNC) continues to sell a USPlabs product containing DMAA known as Jack3D (pronounced “Jacked”) on its website along with the description: “ultra-intense muscle-gorging strength, energy, power, and endurance.”¹ The April 12 *New York Times* follow-up article stated that “Vitamin Shoppe appears no longer to be stocking Jack3d,” but the Committee is now aware of the fact that, while no longer available on the company’s website, Vitamin Shoppe stores continue to sell the product.²

¹ See Natasha Singer & Peter Lattman, *A Workout Booster, and a Lawsuit*, N.Y. TIMES, Feb. 13, 2013, available at <http://www.nytimes.com/2013/02/14/business/death-after-use-of-jack3d-shows-gap-in-regulation.html?pagewanted=all>.

² See Natasha Singer & Peter Lattman, *F.D.A. Issues Warning on Workout Supplement*, N.Y. TIMES, Apr. 12, 2013, available at http://www.nytimes.com/2013/04/13/business/fda-issues-warning-on-workout-booster.html?_r=0.

On April 11, 2013, FDA issued a consumer safety alert noting that the agency had received 86 adverse event reports associated with products containing DMAA, including psychiatric disorders, heart problems, nervous system disorders, and deaths.³ FDA stated that DMAA did not qualify as a dietary ingredient and advised consumers not to buy or use any products containing the stimulant.⁴ FDA has also stated that it can ban an unsafe compound in a dietary supplement, though the agency is required to “undertake a series of lengthy scientific and legal steps” in doing so.⁵ In the interim, FDA is “using all available tools at its disposal” to ensure that DMAA is “no longer distributed and available for sale to consumers.”⁶

To assist the Committee in better understanding why Vitamin Shoppe continues to sell products containing DMAA despite FDA’s warnings about the safety of this amphetamine derivative, please provide the following information by no later than May 31, 2013:

1. All documents and communications in the possession of Vitamin Shoppe relating to whether DMAA is a dietary ingredient under 21 U.S.C. 321(ff)(1).
2. All documents and communications in the possession of Vitamin Shoppe relating to whether DMAA is a dietary ingredient that was lawfully marketed in the United States before October 15, 1994.
3. All documents and communications in the possession of Vitamin Shoppe relating to whether DMAA has been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
4. All documents and communications in the possession of Vitamin Shoppe relating to whether products Vitamin Shoppe sells containing DMAA, when used under the conditions recommended or suggested, will reasonably be expected to be safe.
5. All documents and communications in the possession of Vitamin Shoppe relating to complaints and safety concerns associated with DMAA and/or products Vitamin Shoppe sells containing DMAA.
6. All documents and communications in the possession of Vitamin Shoppe relating to FDA’s actions or communications associated with DMAA and/or products Vitamin Shoppe sells containing DMAA, including, but not limited to, communications between FDA and Vitamin Shoppe.
7. All documents and communications in the possession of Vitamin Shoppe relating to any labeling claims, including, but not limited to, the nature, identity, and strength of

³ See Consumer Update, *Stimulant Potentially Dangerous to Health, FDA Warns*, U.S. Food & Drug Admin., Apr. 11, 2013, [hereinafter “FDA Consumer Update”], available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm347270.htm>.

⁴ *Id.*

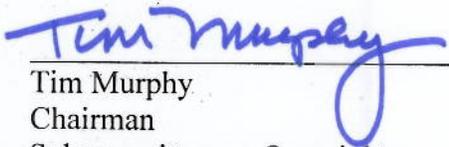
⁵ *Q & A on DMAA in Dietary Supplements*, U.S. Food & Drug Admin., Apr. 19, 2013, available at <http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm>.

⁶ FDA Consumer Update, *supra* note 3.

ingredients Vitamin Shoppe requires dietary supplement makers to make in order for Vitamin Shoppe to sell their products.

An attachment to this letter provides additional information on how to respond to the Committee's request. If you have any questions about this request, please contact Karen Christian or John Stone with the Committee staff at (202) 225-2927.

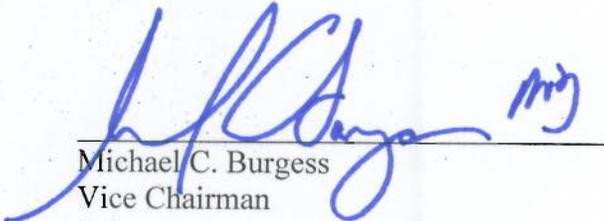
Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations



Joe Barton
Chairman Emeritus



Michael C. Burgess
Vice Chairman
Subcommittee on Oversight
and Investigations

Attachment

cc: The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations