

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 8, 2013

Mr. Joseph M. Fortunato  
President and Chief Executive Officer  
General Nutrition Centers, Inc.  
300 Sixth Avenue  
Pittsburgh, PA 15222

Dear Mr. Fortunato:

Pursuant to Rules X and XI of the U.S. 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 continues to market products containing DMAA, including a product known as Jack3d (pronounced “Jacked”).

In February and March 2013, the *New York Times* published articles highlighting the fact that General Nutrition Centers, Inc. (GNC) continues to sell Jack3d on its website along with the description “ultra-intense muscle-gorging strength, energy, power, and endurance.”<sup>1</sup> The articles also describe how the Department of Defense removed all products containing DMAA from stores on military bases, including over 100 GNC locations. This action was taken after an investigation was initiated into whether the deaths of two soldiers were associated with their usage of Jack3d.<sup>2</sup> Several articles have subsequently been published in military health journals

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<sup>1</sup> Natasha Singer & Peter Lattman, *Is the Seller to Blame?*, N.Y. TIMES, Mar. 15, 2013, at 1, available at [http://www.nytimes.com/2013/03/17/business/a-soldiers-parents-take-aim-at-gnc-and-a-supplement-maker.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2013/03/17/business/a-soldiers-parents-take-aim-at-gnc-and-a-supplement-maker.html?pagewanted=all&_r=0). See also 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>.

<sup>2</sup> See *id.*

based on this investigation. Summarizing the findings, one such article concluded that “this entire scenario is reminiscent of ephedra, which ultimately was banned by the FDA.”<sup>3</sup>

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.<sup>4</sup> FDA stated that DMAA did not qualify as a dietary ingredient and advised consumers not to buy or use any products containing the stimulant.<sup>5</sup> 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.<sup>6</sup> 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.”<sup>7</sup> However, as of May 7, 2013, GNC continues to sell Jack3d on its website.

To assist the Committee in better understanding why GNC 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 21, 2013:

1. All documents and communications in the possession of GNC 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 GNC 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 GNC 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 GNC relating to whether products GNC 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 GNC relating to complaints and safety concerns associated with DMAA and/or products GNC sells containing DMAA.

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<sup>3</sup> Michael J. Eliason et al., *Case Reports: Death of Active Duty Soldiers Following Ingestion of Dietary Supplements Containing 1, 3- Dimethylamylamine (DMAA)*, 177 MIL. MED. 1455, 1457 (2012).

<sup>4</sup> 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>.

<sup>5</sup> *Id.*

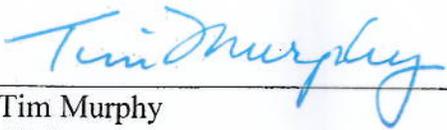
<sup>6</sup> *Q & A on DMAA in Dietary Supplements*, U.S. Food & Drug Admin., Apr. 19, 2013, available at <http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm>.

<sup>7</sup> FDA Consumer Update, *supra* note 4.

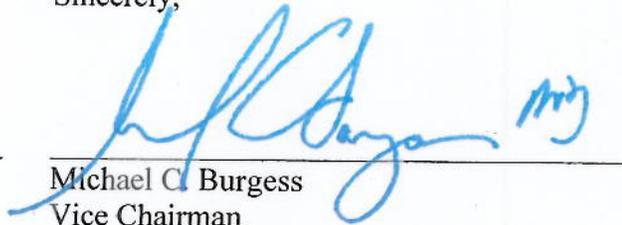
6. All documents and communications in the possession of GNC relating to FDA's actions or communications associated with DMAA and/or products GNC sells containing DMAA, including, but not limited to, communications between FDA and GNC.
7. All documents and communications in the possession of GNC relating to any labeling claims, including, but not limited to, the nature, identity, and strength of ingredients, GNC requires dietary supplement makers to make in order for GNC 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,



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Tim Murphy  
Chairman  
Subcommittee on Oversight  
and Investigations



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Michael C. Burgess  
Vice Chairman  
Subcommittee on Oversight  
and Investigations



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Joe Barton  
Chairman Emeritus

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

Attachment