

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

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

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 response to the Warning Letter, USPlabs submitted several published studies to FDA challenging the agency’s findings.

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.¹ FDA stated that the information USPlabs submitted was “insufficient to defend the use of DMAA as an ingredient in dietary supplements” and advised consumers not to buy or use any products containing the stimulant.² FDA subsequently asserted that it could ban an unsafe ingredient in a dietary supplement, though the agency is required to “undertake a series of lengthy scientific and

¹ 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>.

² *Id.*

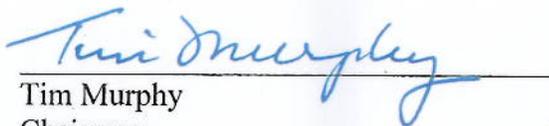
legal steps” in doing so.³ In addition to banning certain ingredients, the agency said that “FDA can also take a seizure action to remove the products from the market or obtain an injunction against a company to prevent it from manufacturing and distributing illegal products.”⁴ That being said, as of May 7, 2013, USPlabs continues to market Jack3d and General Nutrition Centers, Inc. (GNC) continues to sell it.

To assist the Committee in better understanding FDA’s assessment of the safety of DMAA and the agency’s efforts to remove products containing this stimulant from the market, please provide the following information by no later than May 21, 2013:

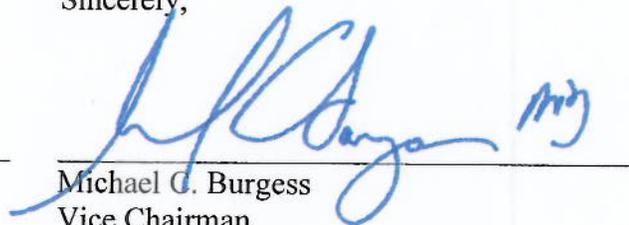
1. All documents and communications referring or relating to DMAA and the agency’s efforts to remove products containing this stimulant from the market.
2. All communications referring or relating to companies marketing and/or selling such products.

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.

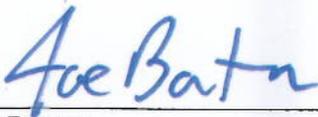
Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations



Michael C. Burgess
Vice Chairman
Subcommittee on Oversight
and Investigations



Joe Barton
Chairman Emeritus

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

Attachment

³ *Q & A on DMAA in Dietary Supplements*, U.S. Food & Drug Admin., Apr. 19, 2013, [hereinafter, “FDA Q&A”], available at <http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm>.

⁴ *Id.*