



Council for Responsible Nutrition

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September 12, 2014

William Correll, Acting Director
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
CPK-1 Bldg, Rm 4C-095
5100 Paint Branch Parkway
College Park, MD 20740
Via Email: william.corell@fda.hhs.gov

Dear Mr. Correll:

The Council for Responsible Nutrition (CRN), the leading trade association for the dietary supplement and nutritional products industry, respectfully requests that FDA examine the regulatory status of a substance marketed as Amp or Amp Citrate (4-amino-2-methylpentane citrate). This substance is being used as an ingredient in dietary supplement products claiming to help increase energy, focus and metabolism^{1,2}. Amp Citrate is also being advertised and perceived as the “next DMAA” and “DMAA alternative”³. As you are well aware, FDA has recently declared DMAA illegal as a dietary ingredient because it lacked a new dietary ingredient (NDI) notification to substantiate its safe use in dietary supplements. There appears to be no NDI notification for Amp Citrate.

Given the availability of Amp Citrate and the advertising of Amp Citrate as a substance similar to DMAA, in chemical structure and in effect, CRN is concerned about the potential dangers to consumers who may be using possible unsafe supplements containing Amp Citrate. As a representative of the dietary supplement industry, we urge FDA to investigate the legitimacy of Amp Citrate as a dietary ingredient. We also urge the agency to use its enforcement authority if it believes this substance and any products containing it are adulterated and take appropriate steps to prevent its further introduction into the U.S. market. We applaud the recent enforcement activities in this area and encourage FDA to devote additional attention to this issue to protect consumers.

¹ Marketing of Amp Citrate by Truvision Health: <http://truvisionhealth.com/products/truweightenergy>.

² Marketing of Amp Citrate by Genomyx, <https://genomyx.com/product/amp-citrate-genomyx>.

³ Perception of Amp Citrate in the marketplace: <http://www.youtube.com/watch?v=FHaFdDCJg9A>;
<http://www.mrsupplement.com.au/amp-citrate>.

Thank you for your consideration of our concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "D. MacKay", with a long, sweeping flourish extending to the right.

Douglas MacKay, N.D.

Scientific & Regulatory Affairs

Council for Responsible Nutrition

cc: Mr. Gary Coody

National Health Fraud Coordinator

Office of Enforcement

Food and Drug Administration

Via Email: gary.coody@fda.hhs.gov