

Despite FDA warning, sports supplements still available online, study reports

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Safety issues remain for 16 cited products, researcher says.

(HealthDay)—DMAA sports supplements have been linked to at least two deaths and the U.S. Food and Drug Administration sent warning letters to 10 manufacturers last spring about a lack of data on their safety, but a new study finds these supplements can still be purchased online.

DMAA (dimethylamylamine) is a pre-workout supplement used by athletes to build muscle. Some research suggests that it may narrow blood vessels, which can elevate blood pressure, and may set the stage for a heart attack. Canada and the U.K have banned DMAA from all supplements.

Now, a small study published online Dec. 3 in the [Archives of Internal Medicine](#) reports that all 16 of the products mentioned in the FDA's warning letters are still available through online retailers.

"The FDA has its wings clipped when it comes to [dietary supplements](#) because they have to prove harm in order to remove a product from the market," explained study author Philip Gregory, an associate professor of pharmacy practice at Creighton University in Omaha, Neb. "I would imagine that the FDA is collecting data on adverse events and slowly building a case for potentially removing the product."

Efforts by *HealthDay* to reach the FDA for comment were unsuccessful.

The original FDA warning letters stated that the companies had not provided sufficient data showing the safety of their supplements, and gave the companies 15 business days to respond.

Gregory searched for products singled out by the FDA on [Google](#), and found that all 16 were still available via online retailers and on sale directly from the manufacturers' websites. In addition, 12 of the 16 were available through General Nutrition Centers (GNC), and eight could be purchased via [drugstore.com](#), the study showed.

People are drawn to DMAA supplements because they provide a quick fix, Gregory said. "The product promises them better results and quickly, [and] this is a pretty tempting proposition for someone who is dead set on adding bulk and getting ripped," he said.

"DMAA is a stimulant so the risks revolve around stimulant-related side effects," he added. "We don't have much specific data on case reports describing [adverse events](#), but generally speaking, adverse outcomes have included psychiatric disturbances, cardiovascular risks such as increased blood pressure, palpitations, arrhythmia, heart attack or stroke."

Duffy MacKay, vice president of scientific and regulatory affairs at the Council for Responsible Nutrition in Washington D.C., said that the

FDA is likely still in discussions with these companies. CRN is a trade group representing dietary supplement manufacturers and ingredient suppliers.

"The FDA can pull these supplements if they think they pose a risk, so at this point the assumption is that the FDA has not come to that conclusion yet," MacKay said. "The CRN would like to see the FDA take the appropriate regulatory action if warranted."

Unless and until they do, consumers will remain confused, he added. "Consumers should at a minimum know what they are taking and follow the dosing instructions on the product's label, and talk to their health care provider about whether this product is right for them," he said.

GNC issued the following statement regarding DMAA supplements sold in their store:

"All DMAA products sold by GNC are manufactured by third-party vendors. GNC is simply the retailer and, like all retailers, relies upon the contractual representations and warranties made by its vendors that the products are safe and compliant with all applicable laws and regulations," the statement said. "GNC believes the products are compliant with all applicable laws and regulations, and are safe when consumed as directed."

Dr. Pieter Cohen, an internist at Cambridge Health Alliance and an assistant professor of medicine at Harvard Medical School, called for a DMAA ban soon after the FDA sent out the warning letters, and he still thinks the products should be banned.

"Sports supplements produce hundreds of millions of dollars in revenue a year," Cohen said. "This entire class of pre-workout [supplements](#), including DMAA, is very suspect and not a single one is proven to boost

athletic performance, and some ingredients have the potential to cause harm. The FDA needs to act and proactively remove the hundreds of products that don't have adequate safety data to support their use."

More information: See the full list of companies that received [U.S. Food and Drug Administration warning letters on DMAA](#).

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