FDA STATEMENT

Statement on warning for women of childbearing age about possible safety risks of dietary supplements containing vinpocetine

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Statement From:

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Español (/news-events/press-announcements/declaracion-de-la-dra-amy-abernethy-y-frank-yiannas-subdelegados-de-la-fda-sobre-una-advertencia)

Today, the U.S. Food and Drug Administration is warning consumers about safety concerns regarding an ingredient called vinpocetine that is found in dietary supplements, specifically concerns about the use of this ingredient by women of childbearing age. According to data reviewed by the FDA, including a recent report (https://ntp.niehs.nih.gov/ntp/about_ntp/trpanel/2019/july/dart03_508.pdf) by the National Institute of Health's (NIH) National Toxicology Program (NTP), consumption of vinpocetine is associated with adverse reproductive effects – in other words, vinpocetine may cause a miscarriage or harm fetal development.

These findings are particularly concerning since products containing vinpocetine are widely available for use by women of childbearing age. That's why today we're advising pregnant women and women who could become pregnant not to take vinpocetine. We are also advising firms marketing dietary supplements containing vinpocetine to evaluate their product labeling to ensure that it provides safety warnings against use by pregnant women and women who could become pregnant.

Vinpocetine is a synthetically produced compound that is used in some products marketed as dietary supplements, either by itself or combined with other ingredients. Vinpocetine may be referred to on product labels as Vinca minor extract, lesser periwinkle extract, or common periwinkle extract. Dietary supplements containing vinpocetine are often marketed for uses that include enhanced memory, focus, or mental acuity; increased energy; and weight loss. Scientists who have studied the effects of vinpocetine on pregnant animals concluded that vinpocetine decreased fetal weight and increased the chances of a miscarriage. The blood levels of vinpocetine measured in the pregnant animals were similar to those reported in people after taking a single dose of vinpocetine, indicating that pregnant women may experience adverse effects from vinpocetine similar to those seen in the pregnant animals.

In some countries outside of the U.S., vinpocetine is regulated as a prescription drug. When products like vinpocetine are sold as dietary supplements in the U.S., they have not been reviewed by the FDA under the safety and effectiveness standards that apply to drug products. This means that the FDA has not reviewed each vinpocetine product, or its labeling, before those products become available to consumers.

In the 1990s, the FDA received several premarket safety submissions (known as new dietary ingredient notifications) for vinpocetine as an ingredient in dietary supplements. In 2016, we requested comment from stakeholders as part of an administrative proceeding to evaluate whether vinpocetine is legal for sale as a dietary

supplement. With the results in NTP's report, it was important to issue today's warning because the availability of dietary supplement products containing vinpocetine has grown and the labels of vinpocetine products often have no warnings about the dangers of miscarriage and harm to fetal development. For the same reasons, the FDA will expedite completion of the administrative proceeding that we began in September 2016.

The dietary supplement market is a growing industry, with sales multiplying ten-fold over the past 25 years and more than half of all Americans taking at least one dietary supplement on a regular basis. This expansion is one reason why earlier this year, the FDA announced new efforts to strengthen the regulation of dietary supplements by modernizing our regulatory framework.

Today's safety warning is just one of many steps the FDA is taking (/news-events/press-announcements/fda-statement-deputy-commissioner-food-policy-and-response-frank-yiannas-new-steps-protect-consumers) to adapt to the realities of the evolving dietary supplement industry. Protecting the public from unsafe dietary supplements remains a top priority for the FDA. We've also created a public-private partnership, the Botanical Safety Consortium, to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. In April, we introduced a new tool, the Dietary Supplement Ingredient Advisory List (/food/dietary-supplement-products-ingredients/dietary-supplement-ingredient-advisory-list), to more quickly alert the public when we become aware of ingredients that appear to be unlawfully marketed in dietary supplements. And finally, just last month, we held a public meeting (/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-discuss-responsible-innovation-dietary-supplements) with our stakeholders to discuss responsible innovation in the dietary supplements industry.

These efforts, along with today's announcement regarding vinpocetine, underscore how the FDA will continue to preserve access to safe, well-manufactured, and accurately labeled dietary supplements, while we protect the American public from potentially unsafe or otherwise unlawful products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- NTP technical report on the prenatal developmental toxicity studies of vinpocetine in Sprague Dawley rats and New Zealand white rabbits (https://ntp.niehs.nih.gov/ntp/about_ntp/trpanel/2019/july/dart03_508.pdf)
- FDA Statement on new steps to protect consumers from unlawful ingredients in dietary supplements (/news-events/press-announcements/fda-statement-deputy-commissioner-food-policy-and-response-frank-yiannas-new-steps-protect-consumers)

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