FDA Issues Warnings to Marketers of Unapproved 'Chelation' Products

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SILVER SPRING, Md., Oct. 14 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today warned eight companies that their over-the-counter (OTC) chelation products are unapproved drugs and devices and that it is a violation of federal law to make unproven claims about these products. There are no FDA-approved OTC chelation products.

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The companies that received the warning letters claim that their products treat a range of diseases by removing toxic metals from the body. Some also claim to treat autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. Some companies that received the warning letters also claim their products will detect the presence of heavy metals to justify the need for chelation therapy.

The drug products involved have not been evaluated by the FDA for treatment of these diseases, and violate the Federal Food, Drug, and Cosmetic Act (FFDCA). Despite the claims of the companies that received warning letters, the effectiveness in treating any of the diseases listed is unsubstantiated. Depending on the condition, when relying on unproven OTC chelation products to treat serious conditions, patients may delay seeking effective medical care.

In addition, there are serious safety issues associated with chelation products, which can alter the levels of certain substances in the blood. Even when used under medical supervision, these products can cause serious harm, including dehydration, kidney failure, and death.

"These products are dangerously misleading because they are targeted to patients with serious conditions and limited treatment op
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