FDA News Release

FDA takes action against 17 companies for illegally selling products claiming to treat Alzheimer's disease

Products make unproven claims for treating multiple diseases and conditions

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Release

The U.S. Food and Drug Administration today posted 12 warning letters and 5 online advisory letters issued to foreign and domestic companies that are illegally selling more than 58 products, many that are sold as dietary supplements, which are unapproved new drugs and/or misbranded drugs that claim to prevent, treat or cure Alzheimer's disease and a number of other serious diseases and health conditions. These products, which are often sold on websites and social media platforms, have not been reviewed by the FDA and are not proven safe and effective to treat the diseases and health conditions they claim to treat. These products may be ineffective, unsafe and could prevent a person from seeking an appropriate diagnosis and treatment.

"Science and evidence are the cornerstone of the FDA's review process and are imperative to demonstrating medical benefit, especially when a product is marketed to treat serious and complex diseases like Alzheimer's. Alzheimer's is a challenging disease that, unfortunately, has no cure. Any products making unproven drug claims could mislead consumers to believe that such therapies exist and keep them from accessing therapies that are known to help support the symptoms of the disease, or worse as some fraudulent treatments can cause serious or even fatal injuries. Simply put, health fraud scams prey on vulnerable populations, waste money and often delay proper medical care – and we will continue to take action to protect patients and caregivers from misleading, unproven products," said FDA Commissioner Scott Gottlieb, M.D. "Today's actions are part of the FDA's larger effort to address the booming growth of the dietary supplement industry through the implementation of modern regulatory initiatives that will enable the agency to preserve the balanced vision of the Dietary Supplement Health and Education Act (DSHEA), enacted by Congress 25 years ago. That law sought to achieve the right balance between preserving consumers' access to lawful supplements, promoting innovation in these products, while upholding our obligation to protect the public from unsafe and unlawful products and holding accountable those actors who are unable or unwilling to comply with the requirements

of the law. Our newest policy efforts will seize the game-changing opportunity to further strengthen the regulatory framework overseeing dietary supplements and will hone in on important steps to both promote industry innovation while upholding the safety of these products as part of our overall commitment to protecting public health."

In a statement issued today, FDA Commissioner Gottlieb also outlined several important new actions and policy priorities the agency will take in the coming months to improve the safety of dietary supplements and purported dietary supplements, including efforts to more rapidly communicate potential safety issues with dietary supplement products with the public, establishing a flexible regulatory framework that promotes innovation and upholds product safety and other, new steps the FDA could consider taking to better ensure product safety and integrity.

The products cited in the warning and online advisory letters posted today are unapproved new drugs and/or misbranded drugs that claim to prevent, treat or cure Alzheimer's disease and a number of other serious diseases and health conditions, and have been sold in violation of the Federal Food, Drug, and Cosmetic Act. The products include a variety of product types, such as tablets, capsules and oils. The companies have been asked to respond to the FDA within 15 days of receipt of the letters, stating how the violations outlined in the agency's letters will be corrected. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction.

As part of the FDA's effort to protect consumers from Alzheimer's disease health fraud, the FDA has issued more than 40 warning letters in the past five years to companies illegally marketing over 80 products making Alzheimer's disease claims on websites, social media and in stores. We've also taken action in recent years against companies and dietary supplements making similar claims for the treatment of serious conditions such as cancer and opioid addiction. Although these companies may have stopped selling the products or making unproven claims, numerous unsafe and unapproved products continue to be sold directly to consumers due in part to the ease with which companies can move their marketing operations to new websites.

The FDA continues to encourage consumers to remain vigilant whether online or in a store in order to avoid purchasing products that claim to prevent, treat or cure diseases without any proof they will work. Health care professionals and consumers are also advised to report adverse reactions associated with these or similar products to the agency's MedWatch program.

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 is also 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.