

address. These products may be ineffective, unsafe, and/or could prevent individuals from seeking appropriate diagnoses and treatments.

“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,” said FDA Commissioner Scott Gottlieb, MD. 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, including efforts to more rapidly communicate potential safety issues to the public, establishing a flexible regulatory framework that promotes innovation and upholds product safety, and other steps the FDA could consider to better ensure product safety and integrity.

The products cited in the warning and online advisory letters have been sold in violation of the Federal Food, Drug, and Cosmetic Act. The products include a variety of types, such

as tablets, capsules, and oils. The companies were asked to respond to the FDA within 15 days of receipt of the letters with information on how the violations will be corrected. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction. The FDA has issued more than 40 warning letters in the past 5 years to companies illegally marketing more than 80 products making AD-related claims on websites, social media, and in stores.

A list of the companies warned is available by link at <https://www.fda.gov/NewsEvents/Newsroom/Press-Announcements/ucm631064.htm>.

U.S. Food and Drug Administration

DOE Selects 4 Companies for ⁹⁹Mo Production

The Department of Energy National Nuclear Security Administration (DOE/NNSA) announced on February 20 that it had completed its evaluation of applications submitted in response to a funding opportunity for production of ⁹⁹Mo without the use of highly enriched uranium (HEU). Based on evaluations and recommendations from an independent technical review panel, DOE/NNSA selected 4 U.S. companies to begin negotiations for potential new cooperative agreement awards. The companies are NorthStar Medical Radioisotopes, LLC (Beloit, WA), SHINE Medical Technologies (Janesville, WI), Northwest Medical Isotopes (Corvallis, OR), and Niowave, Inc. (Lansing, MI). The U.S. Congress has appropriated funds that would allow DOE/NNSA to create cooperative agreements up to \$15 million for each company. The industry partners will match any awarded funding amount.

DOE/NNSA is supporting the establishment of a redundant, reliable domestic supply of non-HEU ⁹⁹Mo. The effort’s goal is to support the companies in achieving the objective of supplying ~3,000 6-day curies of ⁹⁹Mo each week. In addition to these cooperative agreements,

DOE/NNSA also funds the DOE National Laboratories to advance industry efforts to produce non-HEU ⁹⁹Mo within the country.

⁹⁹Mo is used in more than 40,000 medical procedures in the United States every day. In the last decade, supplies have been challenged by the move toward non-HEU ⁹⁹Mo and by frequent production challenges at reactors outside the country. The American Medical Isotopes Production Act of 2012 directed DOE/NNSA to implement a technology-neutral program (i.e., open to any method of ⁹⁹Mo production that does not use HEU) in cooperation with nonfederal entities. “⁹⁹Mo is such a critical tool in health care. Doctors count on it every day,” said U.S. Secretary of Energy Rick Perry. “This industry outreach helps to develop a reliable domestic supply of a vital medical isotope, reduce dependence on foreign imports, and bring new opportunity to the heartland.”

For more information on DOE/NNSA efforts to establish a reliable supply of ⁹⁹Mo without the use of HEU, see <https://www.energy.gov/nnsa/nnsa-s-molybdenum-99-program-establishing-reliable-supply-mo-99-produced-without-highly>.