FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight

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Statement

The use of dietary supplements, such as vitamins, minerals or herbs, has become a routine part of the American lifestyle. Three out of every four American consumers take a dietary supplement on a regular basis. For older Americans, the rate rises to four in five. And one in three children take supplements, either given to them by their parents or, commonly in teens, taking them on their own.

That's why today we are announcing a new plan for policy advancements with the goal of implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years.

I've personally benefited from the use of dietary supplements and, as a physician, recognize the benefits of certain supplements as a part of a comprehensive care plan. It's clear to me that dietary supplements play an important role in our lives as we strive to stay healthy. It's also clear that the U.S. Food and Drug Administration plays an important role in helping consumers make use of safe, high-quality dietary supplements while also protecting Americans from the potential dangers of products that don't meet the agency's standards for marketing.

In the 25 years since Congress passed the Dietary Supplement Health and Education Act (DSHEA), the law that transformed the FDA's authority to regulate dietary supplements, the dietary supplement market has grown significantly. What was once a $4 billion industry comprised of about 4,000 unique products, is now an industry worth more than $40 billion, with more than 50,000 – and possibly as many as 80,000 or even more – different products available to consumers.

DSHEA imposes a number of requirements around the manufacture and labeling of dietary supplements. We know that most players in this industry act responsibly. But there are opportunities for bad actors to exploit the halo created by quality work of legitimate manufacturers to instead distribute and sell dangerous products that put consumers at risk. As the popularity of supplements has grown, so have the number of

entities marketing potentially dangerous products or making unproven or misleading claims about the health benefits they may deliver.

Making healthy choices about diets can have a significant and positive impact on Americans' health. To be able to make those choices with respect to dietary supplements, consumers need to have access to safe, well-manufactured, and appropriately labeled products. One of my top goals is ensuring that we achieve the right balance between preserving consumers' access to lawful supplements, while still upholding our solemn 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.

Today, we're announcing new steps we intend to advance to achieve these twin goals. These steps include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that our regulatory framework is flexible enough to adequately evaluate product safety while also promoting innovation, continuing to work closely with our industry partners, developing new enforcement strategies and continuing to engage in a public dialogue to get valuable feedback from dietary supplement stakeholders.

The opportunity to strengthen the framework that governs dietary supplements couldn't come at a more pivotal time. On the one hand, advances in science and the growth and development in the dietary supplement industry carries with it many new opportunities for consumers to improve their health. At the same time, the growth in the number of adulterated and misbranded products – including those spiked with drug ingredients not declared on their labels, misleading claims, and other risks – creates new potential dangers.

Legitimate industry benefits from a framework that inspires the confidence of consumers and providers. Patients benefit from products that meet high standards for quality.

I'm concerned that changes in the supplement market may have outpaced the evolution of our own policies and our capacity to manage emerging risks. To continue to fulfill our public health obligations we need to modernize and strengthen our overall approach to these products. Toward these goals, the FDA is committing to new priorities when it comes to our oversight of dietary supplements at the same time that we carefully evaluate what more we can do to meet the challenge of effectively overseeing the dietary supplement market while still preserving the balance struck by DSHEA.

As part of our comprehensive efforts, today we sent 12 warning letters and five online advisory letters to companies whose products, many of which are marketed as dietary supplements, are being illegally marketed as unapproved new drugs because the products bear unproven claims to prevent, treat or cure Alzheimer's disease, as well as a number of other serious diseases and health conditions, including diabetes and cancer. Products intended to treat Alzheimer's disease must gain FDA approval before they are sold in order to help ensure they are safe and effective for their intended medical use. Dietary supplements can, when substantiated, claim a number of potential benefits to consumer health, but they cannot claim to prevent, treat or cure diseases like Alzheimer's. Such claims can harm patients by discouraging them from seeking FDA-approved medical products that have been demonstrated to be safe and effective for these medical conditions. In recent years, we've also taken action against companies and dietary supplements making similar claims regarding treatment of serious

conditions such as cancer and opioid addiction. These enforcement actions are just one part of our overall efforts to update our policy framework governing dietary supplements.

At the FDA, we have an obligation to ensure that we're using the resources that we have as efficiently and effectively as we can, and as we engage in discussions about whether our existing resource levels are adequate, I take that obligation very seriously. That's why I recently directed the establishment of a Dietary Supplement Working Group at the FDA, led out of my office and comprised of representatives from multiple centers and offices across the agency. I've tasked this group with taking a close look at our organizational structures, processes, procedures and practices in order to identify opportunities to modernize our oversight of dietary supplements.

Additionally, when the FDA created the Office of Dietary Supplement Programs (ODSP) three years ago, the agency recognized that keeping up with the evolving marketplace meant giving dietary supplement regulation more attention and making it a higher priority. One of the things that this office has done is to articulate the FDA's strategic priorities on dietary supplements to ensure that we're focusing our attention and using our resources in ways that make sense.

Our first priority for dietary supplements is ensuring safety. Above all else, the FDA's duty is to protect consumers from harmful products. Our second priority is maintaining product integrity: we want to ensure that dietary supplements contain the ingredients that they're labeled to contain, and nothing else, and that those products are consistently manufactured according to quality standards. Our third priority is informed decision-making. We want to foster an environment where consumers and health care professionals are able to make informed decisions before recommending, purchasing or using dietary supplements.

In the coming months, we'll be providing additional details on the steps we are taking to continue moving our dietary supplement program forward to implement these priorities. Our new approach benefits consumers by balancing new policies to promote innovation and efficiency in the marketplace for dietary supplements with increased steps to protect the public from potential safety issues.

Today, I'm also announcing the first of several important steps to help advance our important policy goals. Among the steps that we're considering or actively formulating, first are new ways to communicate more quickly when we have concerns that an ingredient is unlawful and potentially dangerous and should not be marketed in dietary supplements. We're developing a new rapid-response tool to alert the public so consumers can avoid buying or using products with that ingredient, and to notify responsible industry participants to avoid making or selling them.

Second, we also need to ensure that our regulatory framework is flexible enough to adequately evaluate product safety while promoting innovation. The key to this effort will be important steps to foster the submission of new dietary ingredient (NDI) notifications. An effective NDI notification process represents the FDA's only opportunity to evaluate the safety of a new ingredient before it becomes available to consumers and helps promote transparency and risk-based allocation of resources. We're continuing to develop guidance for preparing NDI notifications to ensure FDA can thoroughly review the safety of these ingredients. In conjunction with this effort, we're planning to update our compliance policy regarding NDIs.

We know these are important and timely issues and we're also planning a public meeting this spring on the topic of responsible innovation in the dietary supplement industry. I expect the feedback received during this meeting will be essential as we move to modernize our approach toward NDIs. We'll look to address other challenges that may act as barriers to dietary supplement innovation and safety including issues such as what the right incentives might be for establishing dietary supplement exclusivity, and the scope of permitted dietary ingredients. We invite all our stakeholders to share their views on how the FDA should strengthen the dietary supplement program for the future. So, please stay tuned for more information regarding registration and logistics.

Third, as with other commodities that the agency regulates, it's critical that the FDA continue to work closely with our partners in industry to achieve our primary goal of protecting public health and safety. As the dietary supplement industry develops new products and ingredients, advances new delivery systems and innovates in other ways, the FDA must do more to leverage its existing resources and authorities to evaluate these products. This requires collaborative research and a shared understanding. I'm pleased to announce that we've recently created the Botanical Safety Consortium, a public-private partnership that will gather leading scientific minds from industry, academia and government to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. This group will look at novel ways to use cutting-edge toxicology tools, including alternatives to animal testing, to promote the goals of safety and effectiveness we share with consumers and other stakeholders.

Fourth, we'll continue to take actions to protect public health – like those we took today for illegal Alzheimer's disease products – and develop new enforcement strategies, as a key element of our approach to protecting consumers as the risks evolve. We're already making our internal processes more efficient for taking enforcement action when products claiming to be supplements contain unlawful ingredients, including drug ingredients. For example, last April we took strong action to protect consumers from the dangers of dietary supplement products marketed in bulk and containing pure and highly concentrated caffeine. We warned consumers in November to not purchase Rhino male enhancement products because they were unapproved new drugs that contained sildenafil and/or tadalafil, which are among active ingredients in the FDA-approved prescription drugs Viagra and Cialis. During the same month, we issued warnings to companies for unlawfully marketing as dietary supplement products that contained a compound called tianeptine; these products were unapproved new drugs that bore unproven claims that the products could be used to treat opioid addiction. We've also been active with compliance and enforcement efforts against firms that have shown persistent inability to comply with the current good manufacturing practice requirements for dietary supplements, and taking action to protect the public against unsafe imports and recalled products.

Finally, we'll engage a public dialogue around whether additional steps to modernize DSHEA are necessary. We've heard from stakeholders who want to open such a dialogue. While the FDA is committed to leveraging its existing resources and authorities to the fullest extent possible, we believe there may be value in a broader public conversation about whether certain changes to the law might be helpful. We

believe there may be opportunities to modernize DSHEA for the future, while preserving the law's essential balance. For example, some stakeholders have suggested that the statute should be amended to establish avenues for dietary supplement exclusivity and add a product listing requirement. A mandatory listing requirement could provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation. It could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry.

We're interested in hearing other ideas our stakeholders may have, and not just those limited to changes to the law, so we can go about the task of regulating this space in a way that reflects where the industry is today, and continue to safeguard consumers' ability to access safe, compliant dietary supplements for the next 25 years. For example, is it possible to design a product listing regime that helps us protect consumers and level the playing field for responsible industry participants by making it easier for us to take swift action against illegitimate and dangerous products, such as products that are tainted with drug ingredients? And is it possible to do this without disrupting the balance struck by DSHEA, and without imposing any significant new burdens on responsible firms? The answer to these questions may very well be yes. And if that's the case, these are absolutely things that we should be talking about.

I'm confident that the efforts we're announcing today, and the ones that we'll continue to advance in the months and years to come, will help us achieve these goals on behalf of consumers. The steps outlined today highlight both where we are currently and where we look forward to moving toward. We are eager to continue our work with both our industry partners and dietary supplement consumers and will announce more upcoming ideas that we hope to roll out in the near future.

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.