

**COMMENTS OF PHARMA VITE LLC
ON THE ODS 2004-2009 STRATEGIC PLAN**

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Paul Bolar

V.P., Regulatory Affairs

Phannavite LLC

PO Box 9606, Mission Hills, CA 91346-9606

(818) 221-6200

Good afternoon. My name is Paul Bolar and I am Vice President of Regulatory Affairs for Phannavite LLC, a major manufacturer of dietary supplements based in Los Angeles.

We commend ODS on its progress in furthering research on benefits of dietary supplements. In recent years the office has made significant progress on this key objective.

I would like to focus my comments today on the office's fifth major strategic goal, which is "to expand and conduct outreach activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements." As identified in this goal, the ODS has an important and a unique mandate to serve as an authoritative, impartial information resource for consumers, health care professionals and the media regarding emerging scientific issues related to dietary supplements.

Unfortunately, from our vantage point, ODS generally maintains a low profile with public audiences at the most critical times - when breaking news on dietary supplements is published and media and consumer interest is at its peak.

As an example, vitamin E recently received tremendous media attention when its safety was called into question by the release of the Miller meta-analysis in November 2004. Much of the media ignored the substantial body of existing evidence, including 10M recommendations, which confirm the safety and efficacy of vitamin E. Despite the highly questionable validity of Miller's findings, many consumers were spooked by the distorted headlines and alarmist articles that appeared in the mainstream media. The

ensuing confusion and concern created by these reports resulted in an almost immediate 40% drop in vitamin E sales across all brands and channels of trade that remains to this day. The net result is that millions of consumers who previously received benefits from vitamin E supplements completely stopped taking these products. This outcome should be viewed in light of the fact that significant vitamin E deficiencies in the American diet have been well documented in multiple studies, including the most recent NHANES survey. This single, questionable study may have had more impact on the American consumer's perception and consumption habits of an essential nutrient than any other study, and it has the potential to exacerbate an already serious nutritional situation. It is a perfect example of where ODS could have provided significant insights to health care providers, the media and millions of interested consumers.

Unfortunately, the public heard little if anything from ODS on this issue. Even today - 6 months later - the Vitamin E Fact Sheet on the ODS website does not address the Miller analysis. Many consumers still don't know what to do with this information. The Miller study and the resulting media coverage is a prime example of why ODS needs to weigh in aggressively to educate consumers on the scientific process. Consumers need to understand that neither the scientific community nor the general public should view a single analysis as the definitive answer on a supplement's safety or efficacy. Consumers need to recognize that more information and analysis are required and better understand how to put this information into perspective.

Unfortunately, the best opportunity for ODS to make a significant impact on the understanding of the media and consumers on this particular issue has passed. However, other opportunities will inevitably occur. When they do, we encourage ODS to take a more active leadership role and be on the front line, weighing in with timely, accurate information for public audiences who need to hear a balanced, unbiased, authoritative perspective on the latest science.

We therefore encourage ODS to embrace its fifth strategic goal by aggressively expanding its outreach and communication activities. ODS can and should inform and educate the public about dietary supplements and promptly provide a balanced perspective for consumers, health care professionals and the media on emerging scientific issues. In other words, establish ODS as a timely, go-to source of well-balanced, unbiased information on current issues that affect the public's perception of dietary supplements. To this end, we would also encourage ODS to reach out to industry leaders and trade associations to help develop effective communication approaches.