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United States Senate

COMMITTEE ON
GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

Via First Class Mail
and Facsimile # (973) 383-8379

September 27, 2002

Mr. Robert Occhifinto
President
NVE Pharmaceuticals
33 Newton-Sparta Road
Newton, NJ 07860

Dear Mr. Occhifinto:

On Tuesday, October 8, 2002, the Senate Governmental Affairs Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia will hold a hearing entitled "Ephedra: Who is Protecting American Consumers?" The hearing is scheduled to begin at 10:00 a.m. in Room 342 of the Dirksen Senate Office Building in Washington, D.C. I invite you to testify at this hearing.

According to industry sources, over three billion servings of ephedra-containing products were consumed in 1999. These products are promoted for weight loss, energy enhancement, or enhancement of athletic performance. While ephedra-containing herbs have been used in Chinese medicine for over 5,000 years, such use was restricted to short-term use to treat respiratory conditions with generally low doses of ephedra. It is only recently, that ephedra has been promoted for longer-term usage, in higher doses and often in combination with other stimulants. Concomitant with this increased usage for longer-term use, there has been a large increase in adverse events being reported by users of these products and their family members.

This hearing will focus on what U.S. government agencies and private organizations are doing to protect consumers from harm from ephedra-containing dietary supplements. The hearing will also examine the current voluntary adverse event reporting system for dietary supplements and whether such a system is adequate to protect public health.

While the Subcommittee is very interested to hear your general views on these matters, it would assist us if your oral and written statements would address the following specific topics and questions:

1. Please discuss the system that your company has in place to receive adverse event reports from consumers. For the purpose of our questions, an adverse event constitutes any undesirable health-related experience associated with the use of any of NVE's products by a consumer, whether or not considered product-related by NVE.

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2. Since your company's inception, how many adverse health event reports for ephedra-containing products has your company recieved? Please provide the subcommittee with an inventory of these adverse health events, including the number of deaths, cases of heat stroke, cardiac problems, neurological problems including strokes and seizures, psychiatric problems, and gastro-intestinal problems.

3. How many of these reports has your company provided to the FDA?

4. Please advise the subcommittee of the qualifications of the NVE staff who take calls from consumers with health problems that they believe are related to consumption of your products.

5. Please describe the training or guidance that NVE provides staff who are taking consumers' calls with respect to the management of symptoms.

6. The Subcommittee is also interested in hearing about any follow-up actions that your company has taken to investigate any of the serious health effects that some of your consumers report having experienced while using your products.

7. Please describe NVE's policy with respect to selling ephedra-containing products to minors. How does NVE ensure that minors do not purchase your product?

8. Given the fact that ephedra can be addictive and can provide consumers with both a feeling of enhanced well-being and increased energy, does NVE consider it appropriate to market its products to minors, or with names that are identical to the street names for certain illegal drugs?

9. In what media, does your company market its products? Does NVE advertize in youth-oriented magazines such as *Rolling Stone*, *Sports Illustrated*, *Hot Rod*, *Motor Trend*, *Spin*, *Sporting News*, *Sport*, or *TV Guide*?

10. Since 1983, FDA has prohibited the sale of Over-the-Counter drugs containing caffeine in combination with other stimulants, including ephedrine, phenylpropanolamine, or pseudoephedrine. This action was determined to be necessary because of the widespread abuse of these products by consumers seeking to produce effects similar to those produced by substances subject to the Controlled Substances Act (CSA). Many of the products sold by your company combine caffeine with other stimulants, including ephedra and citrus aurantium. Has your company done any research to determine whether its products have abuse potential? What research has your company done to determine the safety of its products?

11. What does your company know about the demographics of its customers? For instance, what is the average age of consumers of NVE's products? Are those consuming NVE products involved in athletic activities?

12. Caffeine is known to cause dehydration. Caffeine, citrus aurantium, and ephedra are all known stimulants of the autonomic nervous system. Has your company done research to look at the dangers of ingestion of such combinations prior to rigorous physical activity? What research has your company done with respect to the potential for heat strokes or cardiac events by those involved in athletic activities who also consume combination stimulant products such as "Yellow Jackets"?

13. What is NVE doing to educate youth about the dangers of ephedra-containing products?

Committee rules require that 100 copies of your prepared statement be submitted 48 hours in advance of the hearing. Accordingly, I would ask that copies of your written statement be delivered to Brian McLaughlin, 439 Hart Senate Office Building, **no later than 10:00 a.m. on Friday, October 4, 2002.** In addition, I ask that you submit your statement via email to Brian_McLaughlin@govt-aff.senate.gov. While your complete written testimony will be included as part of the hearing record, the Subcommittee requests that all oral testimony be limited to five minutes.

The Subcommittee looks forward to hearing your testimony. Thank you for your assistance in this matter. If you have any questions or would like additional information, please contact Anne Marie Murphy at (202) 224-8464 or Marianne Upton at (202) 224-6960.

Sincerely,

Richard J. Durbin
Chairman
Senate Subcommittee on Oversight of
Government Management, Restructuring
and the District of Columbia