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October 21, 2002

Via Fax (202-228-0400)

Hon. Richard J. Durbin
United States Senate
332 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Durbin:

We are writing on behalf of our client, NVE Pharmaceuticals ("NVE"), of Newton, New Jersey, in response to your letter dated September 27, 2002 concerning a hearing held by the Governmental Affairs Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, entitled "Ephedra: Who is Protecting American Consumers."

Background

Its current President and Chief Executive Officer Robert Occhifinto founded NVE in 1980. Over the ensuing 22 years, the company has grown from a small, less than 10 person operation, to its present status as an employer of approximately 100 full time workers. The company is in the midst of a long-planned expansion, at the conclusion of which it anticipates that it will have over 200 full time employees. NVE is presently one of the largest employers in Newton, New Jersey and anticipates that it will be one of the largest employers in Sussex County, New Jersey.

NVE is a member of the American Herbal Products Association ("AHPA") and has undertaken to abide by all of the bylaws and other requirements of that group. As you know, AHPA is the leading trade organization representing marketers of herbal products in the United States. AHPA is a consistent advocate of the responsible marketing, use, and regulation of herbal products in the United States, and NVE joins wholeheartedly in these objectives as they relate to the industry in general and to the

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products marketed by NVE in particular. AHPA has also repeatedly called upon the United States Food and Drug Administration ("FDA") to fulfill its obligations under the law, including promulgating Good Manufacturing Practices and regulations pertaining to the responsible marketing of ephedra-containing products. NVE joins AHPA in this call for promulgation of current Good Manufacturing Practices ("cGMPs").

Ephedra

The majority of the products marketed by NVE contain the Chinese herb ephedra. This herb has a long history of use, dating back thousands of years. The Chinese specifically recognized ephedra's utility in the alleviation of certain bronchial conditions, as well as its mild stimulant effect. Ephedra has been safely used for thousands of years in Asia, Europe and the Americas for these effects.

As with any substance that is pharmaceutically active, especially substances with stimulant effects, proper use of ephedra products is essential. Abuse and/or misuse of any stimulant product is inherently risky and should not be encouraged in any way. It is the nature of these substances, however, that unfortunately leads a few misguided or misinformed individuals to believe that consumption of excessive amounts of ephedra-containing products will provide exponentially enhanced effects without consequences.

As part of its efforts to address this reality, every ephedra-containing product sold by NVE bears extensive warnings, alerting consumers that consumption of amounts in excess of label directions can pose the risk of severe adverse events. Warnings on NVE products specifically note that abuse can cause stroke and heart attack. NVE respectfully submits that these warnings go well beyond those commonly used on over-the-counter drugs such as acetaminophen and ibuprofen.

Significantly, the most recent available Drug Abuse Warning Network (DAWN) Final Estimates Report, prepared by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, reflects that adverse events associated with acetaminophen are the fourth most common cause of emergency room (ER) admissions in the United States, with over 39,165 occurrences in 2001. Ibuprofen was identified as the cause of 17,123 reported ER admissions.

On the other hand, DAWN identifies *ephedrine* (which we will note here due to the common misunderstanding associated with the herb ephedra and the OTC drug ephedrine) as the cause of 728 ER admissions in 2001, while the entire category of nutritional products were identified as the cause of 1,449 admissions. This data clearly demonstrates that, whatever the risk associated with ephedra products, it is a mere fraction of that posed by the OTC products mentioned above.

Post-marketing Surveillance

Your September 27 letter clearly reflects your concerns with post-marketing surveillance activities as they specifically relate to ephedra and to other herbs and dietary supplements in general. NVE recognizes that this is a proper area for concern and that governmental action in this area is essential. Representatives of AHPA and other industry trade associations specifically addressed these concerns, noting deficiencies in FDA's current Adverse Event Reporting (AER) system at a hearing held by the House Committee on Government Reform on May 27, 1999. At that hearing, FDA agreed that its then operational system was in need of improvement, but suggested that it believed the system was good enough to provide the necessary warnings when unsafe products enter the market.

Unfortunately, while that may have been the case in theory, events have proven the contrary to be true. As noted in a report issued by the General Accounting Office (GAO) on August 4, 1999, FDA's system for accepting and investigating AERs associated with dietary supplements was woefully inadequate and subject to abuse by the Agency. This GAO report dealt with FDA's first effort to promulgate a regulation restricting the sale of ephedra-containing products on the basis of individual dose and daily levels of ingestion. As noted by the GAO, however, this proposed regulation, which the FDA represented was grounded upon hundreds of AERs received by the Agency concerning ephedra, was severely flawed by reliance on bad science. Specifically, GAO cited FDA's failure to properly analyze many of the AERs reported to it, accepting numerous unfounded claims as the basis for its proposed rule making. Indeed, a specific analysis of a variety of the AERs reported by FDA by our firm indicated that the Agency was attributing virtually any report submitted to it as factual, no matter how bizarre or regardless of whether the incident involved an expected effect from the herb. For example, our research found the Agency's roster of ephedra related adverse events to include:

A report by a 70 year-old woman that her menstrual cycle had resumed following her use of an ephedra related dietary supplement.

2. An autopsy report reflecting that the decedent had apparently ingested an ephedra product, while the actual cause of death was a "shotgun blast to the chest."

3 Numerous reports of sleeplessness in individuals ingesting multiple doses of ephedra shortly before bedtime, or in conjunction with multiple cups of coffee or other caffeinated beverages.

FDA is presently working to revise its AER system for dietary supplements. AHPA is

actively engaged in this effort, which NVE fully supports

NVE also recognizes the need for the adoption of standardized procedures for the reporting and handling of AERs within the industry. Toward this end, we respectfully submit that it is incumbent upon FDA to promulgate cGMPs for the dietary supplement industry – something it was expressly directed to do as part of the Dietary Supplement Health and Education Act of 1994. Eight years later, we continue to await a draft document from FDA. NVE believes that it is significant that the only substantive efforts to date in this area have come from the industry itself, specifically the Industry Draft cGMP document submitted to FDA and published in the *Federal Register* on February 6, 1997. This document would require manufacturers to establish and follow written procedures describing the handling of all written and oral complaints regarding any supplement the manufacturer produces. A written record (including, where known, the name and description of the product, lot number, name of complainant, nature of the complaint, and reply to the complainant, if any) of the adverse event report would be required by this draft proposal. Such records would be required to be maintained for one year after the expiration date of the product or receipt of the complaint, whichever is later.

While NVE supports AHPA's efforts to secure promulgation of a sensible cGMP regulation, NVE notes that it also supports the notion contained in the industry draft that reporting of AERs to governmental agencies is not mandatory. Until such time as FDA can establish a policy that places supplement AER reports submitted to it on an even playing field with AERs related to the OTC drug industry generally, we do not believe that reporting should be mandatory. FDA should make a determination whether *all such reports* will be treated as confidential or not. We believe that any system that treats AERs for dietary supplements as publicly available while maintaining confidentiality for such reports for OTC products would potentially be vulnerable as arbitrary and capricious. Moreover, in light of FDA's gross mishandling of AERs associated with ephedra products, the wisdom of submitting any such reports to the Agency must be called into question until FDA corrects its approach to these reports.

Specific Questions in the September 27 Letter.

1 Upon receipt of a telephone call from a customer inquiring about or complaining of an adverse reaction that the customer believes is related to one of our products, the call is forwarded to the customer service department, where the customer is advised to discontinue the use of the product immediately, and to seek medical attention, if necessary. The information reported by the customer is recorded in NVE's customer tracking system records. The customer service person is specifically advised not to attempt to

diagnose a medical condition

If the telephone call (inquiry about a suspected adverse reaction adverse reaction or abuse of one of NVE's products) is from a health or medical care provider or poison control person, the call is forwarded to NVE's Operations Supervisor. The Operations Supervisor attempts to identify the entity through fax of its letterhead or other document. Upon receipt of satisfactory identification (usually done while the caller remains on the telephone, depending upon the urgency) the Operations Supervisor discloses product information such as the active ingredients (which are disclosed on NVE's labels). The information, too, is recorded in NVE's customer tracking system records.

Written complaints of a claimed or suspected adverse reaction to NVE's products have been referred to several persons at NVE in the past, and handled as deemed appropriate under the individual circumstances. Such complaints are now referred to one or more of the following for evaluation and appropriate action: the President or his Administrative Assistant, the General Counsel or his Legal Assistant.

2. NVE started maintaining records of so called adverse event reports some time after its inception. Since the company started keeping these records, it has received reports of approximately 40 purported adverse events, and experienced six law suits. These allegations of adverse events should be considered in the context of the sale of more than a billion ephedrine-containing capsules and tablets. We are in the process of reviewing material relating to these claims and litigations, and will provide you with additional information as soon as practicable.

3. Company policy does not provide for turning over information concerning AERs to the FDA, unless such an event would indicate a manufacturing error of such a magnitude as to warrant a product recall. To date, no such recall has been implemented by the company. Moreover, in light of the severe deficiencies in FDA's handling of ephedra related AERs cited in the above-referenced GAO report, NVE does not anticipate changing this policy until such time as FDA has implemented corrective measures and AHPA advises that reporting would be appropriate.

4. Please see response number 1 above

5 Please see response number above

6. NVE has requested that claimants provide copies of their medical records to rule out fraud or history of the very adverse experience claimed. On several occasions, NVE has voluntarily reimbursed individuals (for items such as lost wages and uninsured medical expenses) if they presented what was believed to be a genuine, credible claim of an adverse experience from NVE's product.

7. NVE products are currently labeled in accordance with Texas State law to expressly prohibit sale to minors. NVE labels also bear a warning that the company's ephedra-containing products should be kept out of the reach of children. As members of AHPA, all ephedra products are labeled to prohibit their sale to any individual under the age of 18. To the extent that products are sold at the retail level in violation of any state law prohibiting their sale to minors, NVE encourages appropriate state law enforcement action.

8. NVE does not believe that scientific evidence exists to support the conclusion that ephedra products are addictive.

   We believe that the term "Yellow Jacket" that was prevalent 30 years ago referred to a prescription capsule that was all yellow. NVE's product was black with yellow stripes, resembling the yellow jacket insect that is prominently displayed on the product label. Nevertheless, NVE has ceased distribution of its Yellow Jacket product.

   NVE does not consider it appropriate to market its products to minors, and does not do so.

9. NVE advertises its products on television and radio, as well as in print. NVE has never advertised in any youth oriented medium.

10. NVE is unaware of any evidence suggesting that its products are used by individuals seeking to produce effects similar to substances subject to the Controlled Substances Act. Finally, NVE notes that AHPA's Botanical Safety Handbook does not list caffeine and ephedra as contraindicated for use in the same herbal mixture and that AHPA's policy on the marketing of ephedra-containing products does not contain any such prohibition.

11. The majority of NVE's customers are females 18 to 49 years of age. Many of NVE's products are carried in General Nutrition Centers.

12. NVE has not conducted any research in this area. The Company believes,

   however, that the relatively low number of emergency room admissions that the DAWN data indicates may be attributable to ephedra-containing products suggests that the risk of such events in the absence of misuse of these products is rare.

13. In the future, NVE will urge its trade association to produce educational material designed to discourage youth from using ephedrine-containing products. However, as stated above, NVE's ephedra-containing products are not intended for sale to youth.

If you have additional questions, please direct them to the undersigned.

Very truly yours,
ULLMAN, SHAPIRO & ULLMAN, LLP

Marc S. Ullman

cc: NVE Pharmaceuticals