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October 15, 2002

VIA FEDERAL EXPRESS

Mr. John Taylor
Director, Office of Enforcement
Office of Regulatory Affairs (HFC-200)
Food and Drug Administration
1350 Piccard Drive, Room 450C
Rockville, Maryland 20850

RE: NVE Pharmaceuticals

Dear Mr. Taylor:

We represent NVE Pharmaceuticals ("NVE") in connection with all matters relating to the FDA's inspection of NVE's manufacturing facility, which occurred under a warrant on October 11, 2002. The Compliance Officers involved in this inspection are Joseph F. McGinnis R.Ph. and Richard D. Manney and the Investigators involved are Eric Rothschild and Keith M. Reily. All FDA employees are based out of the Parsippany, New Jersey district office.

We are deeply troubled by the manner in which this inspection took place and wish to bring to your attention the possibility of gross misconduct by the aforementioned FDA employees. We believe there may have been a lack of administrative probable cause to issue the warrant for inspection of NVE's business establishment, and that these FDA employees may have submitted an inaccurate application for an administrative inspection warrant (the "Application") in order to mislead United States Magistrate Judge Hon. Madeline Cox Arleo. Upon your review of facts of this matter, we kindly request that a copy of such Application be sent to my attention at the above listed address.

The following provides a brief timeline of the events leading up to FDA's inspection of NVE:

- On Monday, September 30, 2002, NVE's General Counsel received a facsimile transmission from Senator Richard J. Durbin dated Friday, September 27, 2002 inviting NVE's President, Mr. Robert Occhifinto, to a hearing entitled "Ephedra: Who is Protecting the American Consumer?" scheduled for October 8, 2002. Sen. Durbin's invitation also included a request for written answers to thirteen questions relating to the hearing's subject matter and to NVE's business operation.

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- On Thursday October 3, 2002, NVE's General Counsel responded via both facsimile and e-mail to Mr. Brian McLaughlin (at the request of Sen. Durbin) and to Sen. Durbin stating that Mr. Occhifinto would be attending a trial in the United States District Court for the Southern District of New York ("Federal Court") beginning October 7, 2002 and, accordingly, he will not be able to accept Sen. Durbin's invitation nor will he be able to timely respond to the written questions. NVE's General Counsel clearly indicated, however, that Mr. Occhifinto would be happy to testify and provide written responses to Sen. Durbin's questions at a later date.
- On Friday, October 4, 2002 Sen. Durbin acknowledged the receipt of NVE's October 3, 2002 letter and stated his regrets that Mr. Occhifinto could not attend the hearing.
- On Tuesday, October 8, 2002, Inspectors Rothschild and Reily made an unannounced visit to NVE to conduct an inspection. Since the President, Mr. Occhifinto, and all other top management were attending the trial in the Federal Court, the inspectors were cordially asked to return the next day.
  On Wednesday, October 9, 2002, NVE's President, Mr. Occhifinto had a telephone conversation with Investigator Rothschild explaining to him that he was in Federal Court on October 8, 2002 and that he would like to set a new date for the inspection of NVE.
  On Wednesday, October 9, 2002, NVE's General Counsel sent a letter addressed to Investigator Rothschild via facsimile and regular and certified mail, return receipt requested, confirming the conversation Mr. Occhifinto had with Inspector Rothschild and further stating that after a full day of waiting, no one from FDA called to set up a new appointment or returned for an inspection and that NVE will assist Investigator Rothschild whenever his schedule would allow for an inspection of NVE.
- On Thursday, October 10, 2002, U.S. Magistrate Judge Hon. Madeline Cox Arleo issued a warrant to conduct an inspection of NVE's business establishment after reviewing the Application by Investigator Rothschild and/or other investigators or compliance officers.
  On Friday, October 11, 2002, the warrant was served upon NVE by the aforementioned FDA employees, accompanied by four U.S. Marshals who were carrying firearms, and NVE's offices and manufacturing facility were inspected. NVE was informed that the warrant was necessary since NVE had previously refused the October 8, 2002 inspection.

Pursuant to Section 374 of the Food, Drug and Cosmetic Act, FDA officers or employees, "upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge, are authorized"..."to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment ..." On October 8, 2002, the FDA investigator was not refused this inspection right. The investigator was told that the President and owner of the company along with top management were in Federal Court at that time and the investigator was invited to return the next day when management could be present. This is clearly not a refusal of inspection and should never have been construed as such.

It is an unlikely coincidence that the October 8, 2002 inspection of NVE occurred on the same day as Sen. Durbin's Ephedra hearing in Washington, DC, as well as, on the day that everyone knew NVE's President and owner would be in Federal Court. Accordingly, this initial inspection was particularly and premeditatedly unfair; it was clearly not performed at a reasonable time nor was it performed within reasonable limits or in a reasonable manner.

Furthermore, the correspondence reflects that FDA investigators had ample opportunity to conduct their inspection without the need of a warrant. On multiple occasions, beginning on the original inspection date and continuing through October 9, 2002, the investigators were invited to return for a complete inspection of the NVE manufacturing facility. The investigators, instead, found it necessary to waste the time of a Federal Magistrate by filing an Application that we fear must have been misleading, in order to receive a warrant of inspection of NVE.

We await your full explanation of the actions taken by FDA's employees in reference to NVE as well as a copy of the Application submitted to receive the warrant. Until then, if you have any questions, please contact me. Thank you for your assistance.

Yours truly

ULLMAN, SHAPIRO & ULLMAN, LLP

Robert Ullman

Robert Ullman, Esq.

VIA FEDERAL EXPRESS

cc: Mr. John B. Foret, Jr., Director
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