***NOTE: This is an email sent from Michael Belenchia to his clients and executive staff members following a USFDA QSIT inspection of his facility. The Horizon Phoenix Group has been working with Mike and his team and is pleased to have provided guidance on USFDA matters and QSIT Pre-inspection assessments.***

***We can do the same for you.***

----- Original Message -----

From: Michael Belenchia
To: Our Valued Customers
CC: Executive Staff
Sent: Wednesday, February 01, 2006 11:10 AM

Subject: FDA Inspection

To All,

The FDA was in Needle Specialty Products this week for a QSIT inspection. The inspector informed us on Monday morning that he would be in the plant for the entire week and possibly into next week, depending on how things looked and on what he found. The FDA had last been in our plant during April of 2002 for the same type of audit. That particular audit lasted for 4 days, with the inspector leaving NSP with five FD-483 items. That inspection was closed by the issuance of the EIR in May of 2002 after completing satisfactory responses.

Yesterday afternoon, the FDA inspector unexpectedly terminated the inspection stating that he wanted to wrap up. The reason he gave for terminating the inspection was due to what he had seen and not found. He was extremely happy with the appearance of the plant with respect to cleanliness and organization, inside and out of our manufacturing and support areas. He reviewed all the previous FD-483 items from 2002. He stated that all were completed and corrected to his satisfaction. He reviewed policies, procedures and batch documentation for over 25 batches going back to 2003. He also reviewed other documentation, such as Internal Audit Schedules, Quality Trend Reports, CAPA, and Executive Management Meeting minutes.

He stated that he was extremely pleased with our batch history files and the quality of the documentation and information contained within the documented records. He stated that it was obvious that we operated a very good operation with well managed and executed quality systems, including policies and procedures. Because of that, he stated there was no reason for him to stay any longer. He left Needle Specialty with no FD-483 items.

Needle Specialty is proud and happy to report the results of the inspection. As you all are aware, FDA inspections are very stressful and usually can provide the type of surprises that nobody welcomes. Needle Specialty is proud of our plant and our quality systems that we work diligently on a daily basis to maintain and improve. We do this for ourselves, but mostly for our customers to insure that the product that we provide is something that all involved with can be proud of and feel good about people using.

Thanks for your help and your business.

Michael Belenchia
Director, Quality Assurance & Human Resources
Needle Specialty Products