



Linda [redacted]
President & Chief Executive Officer

November 2009

To Whom It May Concern:

This letter is written as an endorsement of the skills, expertise and professionalism of Jack Garvey and of the quality of the deliverables provided by his firm, Compliance Architects LLC. Upon the recommendation of expert FDA counsel, we selected and retained Compliance Architects from July through November of 2009 to assist [redacted] Corporation with a variety of activities in response to an FDA Warning Letter and FDA 483 received in 2006, and recall-related activities occurring in 2007 through 2009. The purpose of the engagement was to review readiness for an anticipated FDA inspection, and upon receiving the readiness review by Compliance Architects, perform remedial activities to minimize remaining areas of FDA enforcement risk.

Overall [redacted] was extremely satisfied with the performance of the consulting and advisory services, and with the value received. Jack performed a thorough review of the [redacted] activities and helped the company understand where additional areas of risk remained. Jack worked closely and collaboratively with the [redacted] Director of Quality and helped to prioritize the enforcement risk areas to align to operational budget realities, helping [redacted] to use resources cost-effectively.

In addition to the broad risk-based advice on how to best approach the FDA enforcement challenges with limited resources, Jack was able to roll up his sleeves and execute on tactical document-centric activities that were necessary to fix the identified risk areas. This work was done thoroughly and efficiently and provided a solid documentation package for [redacted] to provide to the FDA to review, if necessary.

Based on the foregoing, I would highly recommend Jack and Compliance Architects for assignments requiring expertise and capability in FDA regulatory, quality and compliance related activities. I intend to use Jack's expert advice and counsel again as the need arises.

Sincerely,

Linda [redacted]
President and CEO