March 6th, 2019

FDA INSPECTION ANNOUNCEMENT

Dear Valued Client:

Per Emery Pharma's internal policy, we must notify our customers of any regulatory inquiries and the results of any regulatory investigations.

On November 13th, 2018, FDA investigators John A. Gonzales and Scott N. Lim were present at the Emery Pharma's facility in Alameda, CA to conduct an unannounced general inspection.

The inspection included a tour of our entire facility and testing laboratories, then went into a representative review of our out of specification (OOS) investigations, change controls, analytical packets, and standard operational procedures. Additionally, an assessment of data integrity related to the various computer-based systems were conducted.

The inspection concluded on November 16th, closing out with no observations. The following FDA report has determined that the inspection classification of Emery Pharms is "No Actions Indicated". Based on this inspection, the inspectors considered our facility to be "in an acceptable state of compliance with regard to current good manufacturing practices (cGMP)".

Regards,

Hubert Lin, M.S.

Quality Assurance Officer
Emery Pharma