

Dear Sponsor,

Nelson Laboratories, Inc. is registered with the Federal Drug Administration (1721109) and is regularly audited by the FDA for compliance with current Good Manufacturing Practices (21 CFR part 210, 211) and Good Laboratory Practices (21 CFR part 58 and 40 CFR 160). We are currently in good standing with the FDA. We are also certified to ISO 17025:2005.

We certify that the facility, tests and controls used in the analysis of your products are in compliance with the current Good Manufacturing Practices as codified in 21 CFR 210 and 211 and when requested, the current Good Laboratory Practices as codified in 21 CFR 58 or 40 CFR 160.

We certify that, to the best of our knowledge, neither Nelson Laboratories, Inc. nor its employees connected with the development or submission of any drug application has been convicted of any crime described in section 306, subsections (a) and (b) of the Generic Drug Enforcement Act of 1992. Nelson Laboratories, Inc. does not and will not knowingly use, in any capacity, the services of any person debarred under section 306, subsection (a) and (b) of the Generic Drug Enforcement Act of 1992. We have no convictions to report.

Our most recent audit by the FDA, to ascertain GMP compliance, was conducted 07-08 March 2011, with zero 483 items.



Lillian Webb, MPC, ASQ-CQE
Regulatory Affairs Specialist