



11 Nov 2024

Regulatory Inspection History, GMP and GLP Compliance, and Debarment Statement

Dear Sponsor,

Nelson Laboratories (NL), LLC located at 1500 West Thorndale, Itasca, Illinois 60143, is audited by the U.S. Food and Drug Administration (FDA) according to current good manufacturing practices (GMP), good laboratory practices (GLP), and good tissue practices (GTP), as applicable. We are also currently ISO 17025:2017 accredited by the ANSI- ASQ National Accreditation Board (ANAB) as a testing laboratory.

We certify that the facility, tests, and controls that are used in the analysis of your products are in compliance with the following:

- Current Good Manufacturing Practices, as codified in 21 CFR 210/211 and 820
- Current Good Tissue Practices, as codified in 21 CFR 1270/1271
- Current Good Laboratory Practices, as codified in 21 CFR 58 or 40 CFR 160, when requested
- Current E.U. and TGA Good Manufacturing Practices

7 Year Regulatory Inspection History

FDA:		
2018	06-08 Nov	CBER, CVM
2021	14 Apr	FDA 4003a Document audit
2024	22-25 Jul	GMP

Pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 D.S.C. 335a (k), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), NL certifies that it did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of the Generic Drug Enforcement Act of 1992. No person employed by NL has currently or in the past five (5) years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. NL has not been debarred by the FDA and is not currently involved in any debarment proceeding with the FDA.

Sincerely,

Signed by:

 Signer Name: Matthew Cushing
 Signing Reason: I approve this document
 Signing Time: Dec 2, 2024 | 11:59 AM MST
 5B71CC0352D44BE9A571E4C233A47399

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