Nelson Labs.
A Sotera Health company

14 Mar 2019

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

Dear Sponsor,

Nelson Laboratories (NL), LLC located at 6280 South Redwood Road, Salt Lake City, UT 84123, is audited by the U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), the European Medicines Agency (EMA), and the Australian Government Therapeutic Goods Administration (TGA) 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

5 Year Regulatory Inspection History

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| **FDA:** | | | **EPA:** | | |
| 2014 | 15-25 Jul | GLP | 2016 | 28 Jun | GLP |
| 2015 | 22-25 Jun | CDRH, CVM | **EMA:** | | |
| 2016 | 22-26 Feb | CDRH, CVM, CDER, CBER | 2016 | 27-29 Sep | EU GMP (DMA) |
| 2016 | 04-08 Apr | BIMO | **TGA:** | | |
| 2016 | 12-15 Apr | CBER | 2015 | 20-23 Jan | Tissue GMP |
| 2018 | 21-23 Feb | CBER | 2018 | 17-18 Dec | Tissue GMP |
| 2018 | 27-30 Mar | CDER | | | |

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.

Nelson Laboratories received an FDA warning letter in 2004. Since that time, no warning letters or any other regulatory actions have been issued against Nelson Laboratories.

Sincerely,

Matt Cushing

Matt Cushing
Sr. Director Global Quality
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