



RE: Statement of Compliance to GDUFA Self-Identification Requirement

13 June 2024

Dear Sponsor,

Nelson Laboratories, LLC (NL), a Sotera Health Company, is a provider of full, life-cycle microbiology testing services for pharmaceutical, medical device, natural products, and processed tissue industries. NL’s main facility is in Salt Lake City, Utah, with Sotera Health located in Broadview Heights, Ohio.

Under the Generic Drug User Fee Amendments of 2012 (GDUFA), all facilities involved in the manufacture and testing of human generic drugs are now required to electronically self-identify with the FDA.

GDUFA has a list for the facilities that renew their registration. Our registration can be found on the FDA’s website: [Generic Drug Facilities, Sites and Organization Lists | FDA](#) for the current fiscal year.

DocuSigned by:
Darcy Bulkley
Signer Name: Darcy Bulkley
Signing Reason: I approve this document
Signing Time: Jun 13, 2024 | 10:48 AM MDT
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