

From: Morris, Nevitt
Sent: Tuesday, May 07, 2019 4:09 PM
To: joan.robertson@grifols.com
Cc: Morris, Nevitt; Alicea, Candido; Glen, Jacqueline
Subject: BLA 125683/0 Information Request (May 7, 2019)

Hello Joan:

We have the following Information Request for BLA 125683/0:

Please provide the complete investigation and summary results into Incident #971692 including, but not limited to, your review and assessment of the following: batch production records, SOPs, incident history, CIP and SIP reports, EM data, microorganism identification and assessment, downstream bulk, and final container results.

Please respond to this request by this Friday, May 10, 2019 COB.

Thanks and kindly acknowledge receipt of this Information Request.

Nevitt

Nevitt Morris

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