From: Hoffman, Kelsy
Sent: Thursday, September 20, 2018 3:13 PM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>
Subject: BLA 125563 Information Request

Dear Ms. Mayer,

Regarding 125563 Amendment 32, Section 3.2.P.5.3 – Validation of Analytical Procedures,
Formaldehyde Content – (b) (4) Product:

1) In Section 2.3 "Linearity" is evaluated by (b) (4)

    . Please submit data to demonstrate
    linearity of analytical response against standard and sample concentrations.

2) Please submit the cited validation reports Q_0612176, Q_0613802 and the development report
    Q_0600205.

Please respond to this Information Request by September 30, 2018.

Also, please send an update regarding the timeline for response to our August 30, 2018, Information
Request.

Regards,

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Center for Biologics Evaluation and Research
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