

Email - BLA questions: DI, Linearity and final container, January 7, 2009 - Menveo

From: Fiore, Cara
Sent: Wednesday, January 07, 2009 12:52 PM
To: 'Webster, Christopher'
Cc: Valenti, Elizabeth
Subject: BLA questions: DI, Linearity and final container

Dear Chris,

We would like you to comment on the two issues below on BLA 125300.

- The first is a product comment about linearity, as below:
"The linearity of the assay was not evaluated because the interpolated titres are discrete values and a linear regression cannot be determined in a meaningful way with these values in the chosen experimental design."
Can you please comment because later in the document, on page 54, you describe the linearity of each of the assays as:
"A linear relationship was demonstrated across the working range for all four serogroups with a coefficient of correlation in each case $r \geq 0.99$ "
- The second is on final container: Please submit a template of lot release protocol for the final container
If you can please give me an idea of when you can submit this, it would be helpful.
Thanks!
Cara

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