

Davidson, Mark

From: Davidson, Mark
Sent: Friday, April 14, 2017 11:12 AM
To: 'Rizwana Sproule'
Cc: 'Alex Babayan'
Subject: RE: BLA 125643/0 Rolling Submission: Facility / Equipment Request for Information

Importance: High

Dear Dr. Sproule,

While conducting our filing review, we identified the following potential review issue:

From the Common Technical Document, you have omitted:

Facility / Equipment information related to manufacture, control, and storage of (b) (4) Vector for the (b) (4) , recommended, per Guidance for Industry Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product, January 1999 and Guidance for Industry: M4Q: The CTD – Quality, January 2001 to be included in the Chemistry, Manufacturing, and Controls (reference section: 3.2.A Appendices – Facilities and Equipment).

The referenced DMF, (b) (4) , does not provide the product specific information, as recommended by the guidance and needed for an effective review. Please provide this information by COB April 18, 2017.

Thank You

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