

CMC IR June 21, 2017**Please respond to the comment by Wednesday June 28, 2017:**

During pre-license inspections at (b) (4) it was identified that (b) (4) is a temporary alternative storage site located in (b) (4) for vector product filled at (b) (4). Vector product could be transported either directly to the Morris Plains NJ cell manufacturing facility or shipped to (b) (4) for short term storage.

During the PLI at (b) (4), the FDA inspection team discussed this issue extensively with staff of (b) (4). This is a discussion item of the inspection. The FDA inspection team verbally stated that the following information needs to be submitted to the BLA as an amendment.

- A full description of the storage conditions at (b) (4) related to the (b) (4) vector product.
- A description of whether the storage facility is under cGMP control.
- Detailed SOPs for vector shipping and receiving with diagrams.
- A description of who is responsible for packaging of vector product at (b) (4) for shipping to Morris Plains NJ USA.
- A description of how the chain-of-identity is maintained.
- A description of how the temperature is maintained during shipping.
- A full description of the courier for shipping.
- The Quality Agreement with (b) (4) and the courier service company.
- A description of any training programs for handling the shipping and packaging of the vector product.
- Detailed SOPs for vector shipping and receiving with diagrams.