

## Recommendation – Identification of BLA complaint lots



| Item                                   | Description  |
|--|--|
| <b>A</b> DRY ICE POD                   | Holds the top layer of dry ice   |
| <b>B</b> VIAL TRAYS                    | Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials                    |
| <b>C</b> BOX THAT HOLDS THE VIAL TRAYS | Box within the thermal shipping container that includes the vial trays. This box should not be removed |
| <b>D</b> FOAM LID                      | Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box  |
| <b>E</b> THERMAL SHIPPING CONTAINER    | Outer box of the thermal shipping container  |

### Identifier Options

**195 tray:** **Unable** to apply sticker/signage on frozen trays. Note: Tray label contains QR code.

**Shipping Container:** **Able** to include a leaflet on top inside for identified batches. Approach used with 25pack.

**Electronic via QR codes:** Updates to HCP site (see next slide for details). Allows for updates to lot numbers as variations are approved in BLA.

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