

# Recommendation – Identification of BLA 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.

## Document Approval Record

**Document Name:** 20 August 2021 for CBER- Attachment Infographic- Identification of BL A Compliant Lots

**Document Title:** 20 August 2021 for CBER- Attachment Infographic- Identification of BL A Compliant Lots

<b>Signed By:</b>	<b>Date(GMT)</b>	<b>Signing Capacity</b>
Harkins Tull, Elisa	20-Aug-2021 20:50:50	Regulatory Affairs Approval