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QUERY 1

In reference to the diluent that will be used with your COVID-19 vaccine (sterile 0.9% Sodium Chloride Injection, USP) “2 mL single dose” and “10 mL single dose” vials:

QUERY 1-A

Please update Section 3.2.P.3.1. MANUFACTURER(S) of your BLA to include the manufacturers of each vial size, including their address and FEI numbers.

RESPONSE 1-A

A Section 3.2.P.3.1 Manufacturer(s) [DILUENT] has been added to include the manufacturers’ address of sterile 0.9% Sodium Chloride Injection, USP “2 mL single dose” and “10 mL single dose” vials, including each vial size and FEI numbers.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

3.2.P.3.1 Manufacturer(s) [DILUENT]- New

Previously submitted supporting documentation
QUERY 1-B

Please update FDA Form 356h to include the information related to your diluent manufacturers.

RESPONSE 1-B

FDA Form 356h will be updated to include information related to the diluent manufacturers.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

QUERY 1-C

Please provide a summary of the shipping procedures for the “2 mL single dose” and “10 mL single dose” vials including the origin of distribution, shipping responsible party, carton sizes, description of the shipper (box) and shipping configuration, and the established shipping controls.

RESPONSE 1-C

The diluent is shipped using next day delivery by United Parcel Service (UPS).

See Table 1 for an overview of the origin of distribution, shipping responsible party, carton sizes, description of the shipper (box), shipping configuration and shipping controls for the 0.9% Sodium Chloride Injection, USP 2 mL and 10 mL Single Dose Vials.
Table 1. Overview of Shipping Procedures and Contents for the 2 mL and 10 mL Single Dose Diluent Vials

<table>
<thead>
<tr>
<th>Origin of Distribution</th>
<th>Shipping Responsible Party</th>
<th>Carton Sizes</th>
<th>Description of Shipper (Box)</th>
<th>Shipping Configuration</th>
<th>Established Shipping Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mL</td>
<td>(b) (4) Fresenius Kabi: Package: 25 Vials/Pack</td>
<td>single wall corrugate</td>
<td>Vials packaged in kits with other ancillary supplies (masks, syringes, gloves, etc.) Three 25-count or Eight 25-count packs per shipper</td>
<td>Live 24/7 monitoring of shipment</td>
<td></td>
</tr>
<tr>
<td>10 mL</td>
<td>(b) (4) Hospira: Package; 25 vials/pack</td>
<td>single wall corrugate</td>
<td>Vials packaged in kits with other ancillary supplies (masks, syringes, gloves, etc.) Eight 25-count packs per shipper</td>
<td>Live 24/7 monitoring of shipment</td>
<td></td>
</tr>
</tbody>
</table>
Literature References
None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation
None

Previously submitted supporting documentation
None
FOLLOW-UP TO 05 AUGUST 2021 IR- DILUENTS-QUERY 3)

Additional supplier of the 10 mL container was inadvertently omitted. Reference Table 2.

Table 2. 0.9% Sodium Chloride Injection Container/Closure Information 10 mL vial

<table>
<thead>
<tr>
<th>Primary Packaging Component</th>
<th>Direct Solution Contact (Yes/No)</th>
<th>Description</th>
<th>Manufacturer Name and Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container</td>
<td>Yes</td>
<td>Plastic Vial, 10 mL</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Closure</td>
<td>Yes</td>
<td>Stopper, 20 mm Gray Compound, Snap Plug</td>
<td></td>
</tr>
<tr>
<td>Seala</td>
<td>No</td>
<td>Seal, 20 mm, Flip-Off, Green, Matte Top</td>
<td></td>
</tr>
</tbody>
</table>

a. While integral to the drug product packaging, the aluminum seal is not considered a primary packaging component, as it does not have direct contact with the solution. The seal keeps the elastomeric closure in its proper position in the neck of the vial. It does not have solution contact.

Literature References
None
SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation
None

Previously submitted supporting documentation
None