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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

FDA-CBER-2021-5683-1149578

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

FDA-CBER-2021-5683-1149579

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.

FDA-CBER-2021-5683-1149580

Table 1.   Overview of Shipping Procedures and Contents for the 2 mL and 10 mL Single Dose Diluent Vials

	Origin of Distribution	Shipping Responsible Party	Carton Sizes	Description of Shipper (Box)	Shipping Configuration	Established Shipping Controls
2 mL	(b) (4)		Fresenius Kabi: Package: 25 Vials/ Pack	single wall corrugate	Vials packaged in kits with other ancillary supplies (masks, syringes, gloves, etc.) Three 25-count or Eight 25-count packs per shipper	Live 24/7 monitoring of shipment
10 mL			Hospira: Package; 25 vials/pack	single wall corrugate	Vials packaged in kits with other ancillary supplies (masks, syringes, gloves, etc.) Eight 25-count packs per shipper	Live 24/7 monitoring of shipment

FDA-CBER-2021-5683-1149581

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

Primary Packaging Component	Direct Solution Contact (Yes/No)	Description	Manufacturer Name and Address
Container	Yes	Plastic Vial, 10 mL	(b) (4)
Closure	Yes	Stopper, 20 mm Gray (b) (4) Compound, Snap Plug	
Seal[a]	No	Seal, 20 mm, Flip-Off, Green, Matte Top	

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

FDA-CBER-2021-5683-1149583

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

FDA-CBER-2021-5683-1149584