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QUERY 1

The BLA includes 4 pictures of the saline diluent that will be provided but shipped separately from the vaccine vials. Additional, information regarding the diluent does not appear to be included in the BLA. Based on the pictures provided, the saline diluent is provided in “2 mL single dose” and “10 mL single dose” vials.

- a. With respect to the 2 mL single dose vial of saline, we assume that the end user will extract 1.8 mL to reconstitute a single vial of vaccine. Please confirm and provide the instructions provided with the diluent.
- b. With respect to the 10 mL single dose vial, please submit any instructions provided to healthcare providers.

RESPONSE 1

Pfizer confirms that the saline diluent is provided in “2 mL single dose” and “10 mL single dose” vials.

Pfizer confirms FDA’s assumption in point “a” is correct. The end user will extract 1.8 mL to reconstitute a single vial of vaccine.

The two diluent vials are intended to be used and stored according to their respective approved product labeling. The following text is included in the draft USPI regarding the use of the provided diluent; the same instructions are provided regardless of vial size.

- Dilute the vial contents using 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form COMIRNATY. Do not add more than 1.8 mL of diluent.
- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Vials of sterile 0.9% Sodium Chloride Injection, USP are provided but shipped separately. Use the provided diluent or an alternate brand of sterile 0.9% Sodium Chloride Injection, USP as the diluent.

The text below is newly proposed and will be provided in the updated draft USPI.

“Provided diluent vials are single-use only and should be discarded after 1.8 mL is withdrawn. Do not use provided diluent vials to dilute multiple vials of COMIRNATY.”

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation-

None

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QUERY 2

Also, please clarify if providers can reconstitute 2 or more vials of vaccine with saline from a 10 mL single dose vial.

RESPONSE 2

Providers should not reconstitute 2 or more vials of the vaccine with saline from a 10 mL single dose vial. The provided 10 mL single use diluent vials are intended to be used to dilute a single vial of vaccine, and the remainder should be discarded. The following statement has been proposed as an addition to the USPI:

“Provided diluent vials are single-use only and should be discarded after 1.8 mL is withdrawn. Do not use provided diluent vials to dilute multiple vials of COMIRNATY.”

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

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QUERY 3

Lastly, please provide the container/closure information for each of these vials and information regarding the number of permissible punctures of the vial stopper.

RESPONSE 3

Both diluent vials are single use plastic vials with elastomeric stoppers. The intended use of both diluent vials allows for a single puncture of the vial stopper.

Table 1. 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	(b) (4)
Seal ^a	No	Seal, 20 mm, Flip-Off, Green, Matte Top	(b) (4)

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.

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

Primary Packaging Component	Direct Solution Contact Yes/No	Description	Manufacturer Name and Address
Container	Yes	Plastic Vial 3ml	(b) (4)
Closure	Yes	Stopper, 20 mm Gray , (b) (4) Stopper, 20 mm (b) (4) Stopper, 20 mm Gray, (b) (4)	(b) (4)
Seal	No	Seal, 13mm, Aluminum Crimp Flip Cap Seal Seal 13mm, Aluminum Flip-off Seal	(b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

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QUERY 4

If the requested information above is provided in the BLA, please provide the section(s).

RESPONSE 4

The requested information above was not provided in the BLA. Instructional text as above is now added to the draft USPI.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None