The review team has the below information request for you regarding your diluent suppliers.

QUERY 1

Due to the Warning Letter (reference WL 320-20-31 issued 03/25/2020) and Official Action Indicated status of Pfizer Healthcare India Pvt. Ltd. (FEI# 3008316085), the Agency will not approve the diluent supplied from that manufacturer as part of your BLA. Please acknowledge this notification and remove all references to this supplier from the BLA, including in the recently added Diluent Manufacturers table.

RESPONSE 1

Pfizer acknowledges confirmation of this request and Pfizer Healthcare India Pvt. Ltd is removed from the Diluent Manufacturers table. The Diluent Manufacturers table in Section 3.2.P.3.1 Manufacturer(s) (DILUENT), has been updated.

An updated Form 356H is also provided.

Also, the table containing the supplier of the 10 mL vial has been updated by deleting the 10 mL Vial supplier to Pfizer Healthcare India Pvt. Ltd. Table 1 as amended with the updated container closure supplier information is shown below for reference.

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	

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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
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.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

Section 3.2.P.3.1 Manufacturer(s) (DILUENT), replaced

Previously submitted supporting documentation

None

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