BNT162b2 - BLA 125742

Diluent Labeling

May 2021

1. INTRODUCTION

Reference is made to the following:

- Pfizer/BioNTech Briefing Document submitted 18 February 2021 to BB-IND 19736 for a Type C Meeting regarding the Ready-to-Use (RTU) and lyophilized formulations of the BNT162b2 vaccine.

- CBER's 10 March 2021 Written Response to Pfizer/BioNTech's Questions for the Agency contained in the Briefing Document

- Pfizer/BioNTech's 19 March 2021 response to CBER's 10 March 2021 Information Request, specifically our clarification question to FDA Additional Comment 1, "Pfizer/BioNTech acknowledges FDA request to co-package the 0.9% Sodium Chloride Injection, USP diluent with the current frozen liquid Covid-19 vaccine drug product for licensure. However due to the extremely cold storage conditions required to maintain requisite stability for the frozen drug product, co-packaging diluent is not possible at this time, due to the risk to the integrity of the vials with freezing at very low temperatures. To address CBER's request, Pfizer proposes to ship necessary quantities of 0.9% Sodium Chloride Injection, USP diluent in parallel to shipments of the Covid-19 vaccine drug product, with arrivals synchronized so that diluent is delivered before vaccine is delivered. The 0.9% Sodium Chloride Injection, USP diluent will be labelled for exclusive use with the Comirnaty™ Covid-19 vaccine."

- CBER's 06 April 2021 agreement with the aforementioned proposal.

- Part 1 of the Original Submission of the rolling Biologics License Application (BLA) for the BNT162b2 vaccine candidate developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age submitted on 06 May 2021.

The purpose of this document is to describe and present the proposed labeling of the 0.9% Sodium Chloride Injection, USP diluent to be used with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)].

2. IDENTIFICATION OF DILUENT FOR USE WITH COVID-19 VACCINE DRUG PRODUCT

Reference is made to the Emergency Use Authorization 27034 for the Pfizer-BioNTech COVID-19 Vaccine. The 0.9% Sodium Chloride Injection, USP diluent for BNT162b2 is supplied by Pfizer to the US government for distribution to vaccine administrators. Currently, the diluent is supplied in 3 mL glass vials manufactured by Fresenius Kabi LLC. There is also an alternate source of diluent that may be supplied separately in 10 mL vials, if needed, that are manufactured by Hospira, Inc.

For the licensed commercial vaccine, a similar approach will be used as was done under the EUA. Pfizer/BioNTech will provide the same 0.9% Sodium Chloride Injection, USP diluent manufactured by Fresenius Kabi LLC or the Hospira saline diluent (if needed). The saline

diluent will be supplied separately to healthcare providers (shipped in parallel with shipments of the Comirnaty, with arrivals synchronized so that diluent is delivered before the vaccine is delivered).

Cartons of the saline diluent will be clearly labeled to indicate that it is for use with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)] specifically:

Cartons of the 0.9% Sodium Chloride Injection, USP diluent supplied by Fresenius Kabi LLC will be ink print stamped on the side of the carton opposite the Fresenius Kabi diluent label with the following text: "For Use with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)]." Attachment 1 shows an image of the Fresenius Kabi diluent carton. Attachment 2 shows an image of the For Use with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)] stamp. The information is printed from a domino printer in dot matrix font in a default font size of 7. The ink stamp text is in black. No physical label can be applied, as the packaging line is fully automated and does not have this capability.

Cartons of the 0.9% Sodium Chloride Injection, USP diluent supplied by Hospira Inc., will be labeled on the side of the carton opposite the Hospira diluent label. The label will state: "For Use with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)]." Attachment 3 shows an image of the Hospira diluent carton. Attachment 4 shows the artwork for the "For Use with COMIRNATY™ [COVID-19 mRNA Vaccine (nucleoside modified)]" label.

Document Approval Record

Document Name:	COVID-19 Vaccine 2021 Proposed Labeling - FDA - Comirnaty Diluent
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Signed By:	Date(GMT)	Signing Capacity
Nosal, Roger	17-May-2021 10:55:14	Business Line Approver