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**Pfizer Inc.**  
275 North Field Drive  
Lake Forest, IL 60045

December 17, 2021

### **Packaging and Label Changes for Propofol Injectable Emulsion 1% (contains Benzyl Alcohol), Multiple Presentations**

Dear Customer,

Pfizer Hospital is notifying you of an impending change to the packaging and label of Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) Single Patient Use Vials. Pfizer is updating the labels for **Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 200 mg/20 mL** (00409-4699-30), **500 mg/50 mL** (00409-4699-33), and **1000 mg/100 mL (10 mg/mL)** (00409-4699-24) **Single Patient Use Vials** by adding “USP” to all manufactured product going forward, as seen in the label images in Figure 1 below. Customers may begin to receive product with this new label in mid- to late-December 2021, depending on presentation.

In addition, Pfizer Hospital has also changed the seal color to a slightly different shade of blue for **Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 200 mg/20 mL (10 mg/mL) Single Patient Use Vial**, NDC 00409-4699-30, as seen in the seal images in Figure 2 below. Customers may begin to receive product with the new seal color as soon as mid-January 2022.

There is no change to the NDC number, indication, formulation, or pricing of these products. Propofol Injectable Emulsion, USP 1% (contains EDTA) presentations produced by Pfizer Hospital are not undergoing any changes at this time.

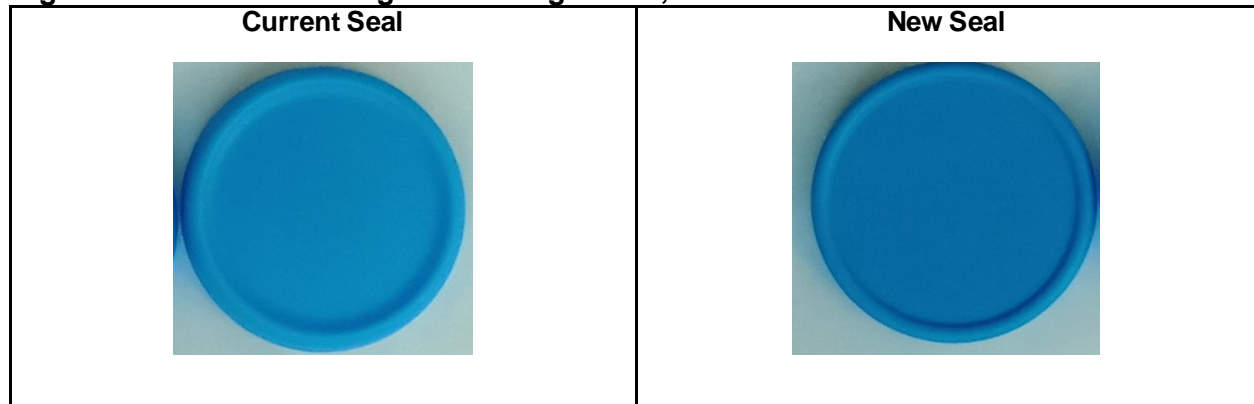
**Figure 1: Label Change for All Presentations**

Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 200 mg/20 mL (10 mg/mL) Single Patient Use Vial 00409-4699-30 <b>Current Label</b>	Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 200 mg/20 mL (10 mg/mL) Single Patient Use Vial 00409-4699-30 <b>New Label</b>
<p>20 mL For Single Patient Use Only</p> <p><b>PROPOFOL</b> Injectable Emulsion 200 mg/20 mL (10 mg/mL)</p> <p>CONTAINS BENZYL ALCOHOL SHAKE WELL BEFORE USING.</p> <p>AP/DRUGS/08/2013 M.L.No. 08/VP/AP/2013/FIG Distributed by Hospira, Inc. Lake Forest, IL 60045 USA</p> <p>Rx only NDC 0409-4699-30</p> <p><b>• CONTAINS BENZYL ALCOHOL, which inhibits microbial growth up to 12 hours, discard within 12 hours of opening</b> • Use strict aseptic technique</p> <p><b>FOR INTRAVENOUS ADMINISTRATION</b> Each mL contains propofol 10 mg; soybean oil 100 mg; glycerin 22.5 mg; egg lecithin 12 mg; benzyl alcohol 1.5 mg and sodium benzoate 0.7 mg added, pH adjusted with sodium hydroxide. Sterile, nonpyrogenic. Dosage: See package insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Do not freeze. Discard unused portion.</p> <p>PAAL0984</p>	<p>20 mL For Single Patient Use Only</p> <p><b>PROPOFOL</b> Injectable Emulsion, USP 200 mg/20 mL (10 mg/mL)</p> <p>CONTAINS BENZYL ALCOHOL FOR INTRAVENOUS ADMINISTRATION SHAKE WELL BEFORE USING.</p> <p>AP/DRUGS/08/2013 M.L.No. 08/VP/AP/2013/FIG Distributed by Hospira, Inc. Lake Forest, IL 60045 USA</p> <p>Rx only NDC 0409-4699-30</p> <p><b>• CONTAINS BENZYL ALCOHOL, which inhibits microbial growth up to 12 hours, discard within 12 hours of opening</b> • Use strict aseptic technique</p> <p>Each mL contains propofol 10 mg; soybean oil 100 mg; glycerin 22.5 mg; egg lecithin 12 mg; benzyl alcohol 1.5 mg and sodium benzoate 0.7 mg added, pH adjusted with sodium hydroxide. Sterile, nonpyrogenic. Dosage: See package insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Do not freeze. Discard unused portion.</p> <p>PAAL0984</p>

<p>Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 500 mg/50 mL (10 mg/mL) Single Patient Use Vial 00409-4699-33 <b>Current Label</b></p>	<p>Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 500 mg/50 mL (10 mg/mL) Single Patient Use Vial 00409-4699-33 <b>New Label</b></p>
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<p>Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 1000 mg/100 mL (10 mg/mL) Single Patient Use Vial 00409-4699-24 <b>Current Label</b></p>	<p>Propofol Injectable Emulsion 1% (contains Benzyl Alcohol) 1000 mg/100 mL (10 mg/mL) Single Patient Use Vial 00409-4699-24 <b>New Label</b></p>
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**Figure 2: Seal Color Change for 200 mg/20 mL, NDC 00409-4699-30**



If you have any questions regarding this notification, please contact our Customer Service Department at 1-844-646-4398 or via email at [PICustomerServices@pfizer.com](mailto:PICustomerServices@pfizer.com).

Thank you,

Meera Bhavsar  
Vice President, US Sterile Injectables Portfolio Lead  
Pfizer Hospital Business Unit U.S.