

# Cold Chain FAQs for Customers

## **Q1. Why did Cardinal Health standardize the packaging for all refrigerated pharmaceuticals?**

A1. After several years of extensive research, Cardinal Health decided to make a significant change in the way we package and ship refrigerated pharmaceuticals to our customers. The purpose of these changes was to improve the integrity of refrigerated products being delivered through the use of tested and performance qualified packaging. Cardinal Health Puerto Rico is proud to be the first wholesaler in Puerto Rico to be replacing the traditional gel-packs and corrugated boxes with reusable, durable, insulated plastic totes combined with special thermal panels designed and tested to maintain the labeled product temperature range of 2 to 8 degrees Celsius from our warehouse to your business. With the implementation of this change, Cardinal Health is raising the standard of cold chain packaging and distribution in Puerto Rico.

## **Q2. How does the new packaging solution work?**

A2. The refrigerated pharmaceuticals will arrive in a performance qualified insulated tote with phase change panels designed and tested to keep the product between 2°C-8°C (36°F-46°F) during shipment. The phase change panels look like sheets of freezer pops and will maintain the product within the labeled temperature storage range from the time it ships from a distribution center to the time it reaches a customer.

## **Q3. What is the difference between the “green” and “orange” phase change panels?**

A3. For years, the industry standard for the packaging of refrigerated pharmaceuticals was the use of frozen water-based gel-packs inside of foam containers. The challenge is that frozen water, at zero degrees Celsius is actually colder than the storage range of 2 to 8 degrees for refrigerated pharmaceuticals. This initial “cold blast” was necessary to keep the temperature from rising above 8 degrees too quickly. The problem that we discovered in our testing was that the traditional gel-packs have a difficult time maintaining this narrow temperature range required for refrigerated pharmaceuticals. Additionally, foam coolers, corrugated boxes and gel-packs create a lot of waste that end up in landfills.

The phase change materials are compounds that liquefy and solidify at specific temperatures. During the process of liquefying and solidifying within a set temperature range, phase change materials absorb, store, and release large amounts of energy. These natural properties called latent heat energy help maintain a product's temperature and buffer it from temperature swings. Phase change materials recharge as ambient temperatures fluctuate, making them ideal for maintaining the 2 to 8 degree range for refrigerated pharmaceutical packaging. The phase change panels that you will be receiving in our cold chain totes have the unique ability to maintain 2 to 8 degrees for an extended period of time. The new panels are made of a proprietary formulation of natural vegetable-based phase change materials that solidify, or freeze, at 4 degrees Celsius and maintain 2 to 8 degrees inside the cold chain boxes well beyond the delivery times to your location.

## **Q4. Are colder temperatures better for refrigerated pharmaceuticals?**

A4. No. The majority of pharmaceuticals cannot be exposed to freezing temperatures below 0°C (32°F) without the loss of potency, reduced efficacy or reduced expiration dates. In fact, many vaccines and proteins are completely destroyed by freezing temperatures. The Center for Disease Control (CDC) reports that freezing temperatures are the greatest danger to vaccines.

**Q5. What happens if when I receive the refrigerated product with the new orange thermal packs my product is not as cold as I received it with the frozen gel-packs?**

A5. As previously mentioned, the majority of pharmaceuticals cannot be exposed to freezing temperatures below de 0°C (32°F) without the loss of potency, reduced efficacy or reduced expiration dates. Frozen water, at zero degrees Celsius is actually colder than the storage range of 2 to 8 degrees for refrigerated pharmaceuticals. Therefore, when you receive your product with the new orange phase change panels freeze the product should feel cool, not cold or warm. The orange phase change panel may arrive at your location, still feel frozen, slushy or cold with slushy particles; or they may be a cool refrigerated liquid. All of these conditions are qualified to our tested standard. Keep in mind that our goal is to maintain your product between 2 and 8 degrees. Remember, if you find “solidified” or frozen panels next to your product, this is okay since these freeze at 4 degrees and maintain this temperature even when exposed to temperatures well below 0 degrees.

**Q6. Is the substance inside the phase change panels toxic?**

A6. No. The material is completely safe and is a USDA-registered food product. It is non-toxic, environmentally friendly, and reusable. Please note: The substance is vegetable-oil based, and there may be a reaction if it comes into contact with the Styrofoam that is packed within the tote. However, it is completely safe and non-toxic.

**Q7. How do customers return items to Cardinal Health using this process?**

A7. Complete instructions for returning refrigerated items to Cardinal Health accompany the tote and can also be found on [www.cardinalhealth.pr/unidos](http://www.cardinalhealth.pr/unidos).

**Please note: Any item not packaged correctly cannot be returned to stock and will need to be destroyed by Cardinal Health.** The proper packaging uses panels the customer received from Cardinal Health and is designed to ensure that the package maintains the appropriate temperature range. Customers should not use other temperature controlling packaging (e.g., water-based, frozen gel packs) in conjunction with – or in place of – these panels as it deteriorates the performance of the panels.

We want to ensure that Cardinal Health is keeping the supply chain safe and preventing possible spoiled or adulterated product from re-entering the supply chain. For detailed information on this return process, including how to pack the totes, please view the videos and documents on [www.cardinalhealth.pr/unidos](http://www.cardinalhealth.pr/unidos).

**Q8. What should a customer do if a panel breaks/leaks?**

A8. The customer should take a few steps if one of the panels breaks or leaks:

- Contain the spill
- Clean up with hand soap and water (Remember the panels are made of a non-toxic natural vegetable based material)
- Do not dispose of the panels or the tote
- Place the damaged panel in a plastic Ziploc bag
- Report it to Cardinal Health Customer Service Department at 787.625.4200
- Please return the panel to Cardinal Health so we can return it to the vendor

**Q9. Are frozen pharmaceuticals handled differently?**

A9. At this time, there is no change to how frozen pharmaceuticals will be delivered or returned. They will continue to utilize the traditional water-based gel-packs and must be returned the same way. We are currently working on a process for how we will deliver and return frozen product and will share this information as soon as we have it available.