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January 30, 2017

Notification to Aplicare Customers

On Dec. 15, 2016, the U.S. Food and Drug Administration (FDA) issued a warning letter to Aplicare relating to manufacturing operations at our Meriden, Conn., manufacturing facility. We take this matter very seriously and have provided a written response to the FDA on Jan. 24, 2017 outlining the steps we have taken and will continue to take to ensure the quality, safety and efficacy of our products.

This letter is to notify you of changes coming to several of our Aplicare product labels. In view of the FDA's feedback, Aplicare will be revising the product packaging labels for the povidone-iodine, alcohol-based, skin protectant and benzalkonium chloride offerings.

Starting June 1, 2017, Aplicare will begin shipping products with the following changes:

1. **Povidone-iodine products** (PVP-I Liquid Pouches, Prep Pads, Swabsticks, Sponges, and Ointment):
    a. Revised from "*antiseptic sterile solution"* to "*antiseptic non-sterile solution"*
    b. New part numbers and NDC numbers

2. **Alcohol-based products**:
    a. Removal of *"sterile unless opened or damaged"*
    b. New part numbers

3. **BZK products:**
    a. Replacement of benzalkonium chloride with cleansing
        i. Cleansing Pad
        ii. Cleansing Swabstick
        iii. Cleansing Towelette
    b. Revision of the Product Information to include:
        i. Use as a topical cleanser
    c. New part numbers

With these changes, Aplicare will continue to provide our customers with the high-quality, effective and safe products they have relied upon for years.

If you have any questions please contact:

Aplicare Customer Service: 800-760-3236 or AplicareCustomerService@clorox.com

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