



**DebMed USA, LLC**

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**Subject: Final FDA Rule: Safety and Effectiveness of Healthcare Antiseptics**

January 5, 2018

Dear Valued Customer,

The U.S. FDA has been conducting an ongoing review of OTC antiseptic active ingredients to ensure they are safe and effective. On December 19, 2017, the U.S. FDA issued the long expected final rule for “Safety and Effectiveness of Healthcare Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use” in the Federal Register. In this rule, FDA determined that in addition to several other antiseptic active ingredients, Triclosan, a widely used antiseptic agent, must be phased out of Over-the-Counter antiseptic wash products for **healthcare applications** due to a lack of sufficient safety and efficacy data.

The FDA is deferring the final rulemaking on the following six commonly used antiseptic ingredients: ethyl alcohol, isopropyl alcohol, povidone-iodine, benzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX). The deferral for these ingredients is meant to provide time for manufacturers to provide the FDA with the data needed to confirm the safety and efficacy for these active ingredients. DebMed is optimistic that the required safety and efficacy data will be generated for these six ingredients thereby allowing hand hygiene products containing these actives to continue to be marketed.

**Triclosan – What’s Next**

As an FDA registered manufacturer, we have one year to comply with the ruling by ceasing to manufacture products with Triclosan to ensure no DebMed products containing this active are available after December 20, 2018. Our account managers will work with each customer to understand their infection prevention goals and help them evaluate the best Triclosan Free DebMed product/s to achieve these goals.

**DebMed’s Position**

In anticipation of the FDA making this ruling on Triclosan, DebMed has developed several new antimicrobial soaps to replace Triclosan soaps. These formulas have been well accepted by users, are mild to the skin and very efficacious.





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**DebMed's Triclosan Free Antimicrobial Soaps**

- **Acute Kare**® (active 1% PCMX)
- **BactoShield**® 2% CHG (active Chlorhexidine Gluconate)
- **Kindest Kare**® Advanced Antimicrobial Foam Handwash (active Benzalkonium Chloride)
- **Kindest Kare**® Advanced Antimicrobial Handwash liquid (active Benzalkonium Chloride)

In addition, if your facility is looking to move to a non-antimicrobial soap, DebMed offers a range of scented and non-scented products to meet your needs.

Your DebMed Account Manager will be in contact with you to discuss product alternatives and transition planning, but you may contact them directly as well.

Our R&D and technical support teams are available to answer all your questions. Please send your requests directly to [customerservice@debmed.com](mailto:customerservice@debmed.com).

We will do everything we can to make the transition from Triclosan based soaps to an alternative as easy as possible and provide an effective soap that your staff will love.

Sincerely,

Ron Chappuis  
Vice-President, Marketing

Corinne Van Kampen  
Group Regulatory Manager – North America