

# TECHNICAL BULLETIN

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## To: All Distributors

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Spartan Chemical has recently commercialized our first OTC drug product

- 3337 Lite 'n Foamy® Eucalyptus Mint Sanitizing Hand Wash
- 3338 Lite 'n Foamy® Lemon Blossom Hand Sanitizer
- 3339 Lite 'n Foamy® E2 Sanitizing Hand Wash
- 3340 Lite 'n Foamy® E3 Hand Sanitizer



Spartan's Lite'n Foamy anti-bacterial hand wash and sanitizer products are regulated by the FDA and considered to be an "Over-the-Counter" "OTC" drug. Anti-bacterial hand care products like the Lite'n Foamy hand wash and sanitizers are formulated to comply with the FDA's Tentative Final Monograph for antiseptic drug products. **This applies to all competitive anti-bacterial products as well.**

### Selling Antibacterial Handcare

- Many customers of these products may inquire about antimicrobial efficacy against specific organisms. Example: Kills 99.99% of Staphylococcus Aureus. This request may seem reasonable, however, the FDA considers making specific antimicrobial claims as a claim of preventing infection by the organism in humans. Making these claims is prohibited and if made may result in FDA enforcement action, possibly requiring Spartan to recall the product from the market.
- The only claims that can be made are on the product label and product bulletin. "For hand (sanitizing) (washing) to decrease bacteria on the skin".
- Your competitors must comply with the same regulations and cannot make specific organism claims either.
- While specific efficacy claims are prohibited under the FDA's Final Tentative Monograph, Spartan's Lite'n Foamy products have been tested against several common microorganisms and been found to be effective.

### For Your Reference

Below is a FDA news releases about specific antimicrobial claims that resulted in issuance of multiple warning letters to various firms that may have required product recalls.

### FDA NEWS RELEASE

The U.S. Food and Drug Administration issued warning letters to companies that manufacture and market over-the-counter (OTC) drug products, including hand sanitizers that claim to prevent infection from methicillin-resistant Staphylococcus aureus bacteria (MRSA). Labeling and marketing materials for the affected products claim that they can prevent infection from other disease-causing agents. In addition, the labeling of some of the firms' hand sanitizing drug products make claims related to preventing infection from E.coli and/or H1N1 flu virus. The FDA does not have sufficient evidence demonstrating that these products are safe and effective for these purposes...[more](#)

Best Regards,

Cali Sartor  
Director of Marketing  
Spartan Chemical Company, Inc.