



Subject: New FDA Ruling on Antibacterial Hand Wash Products

September 6, 2016

Dear Valued Customer,

On Friday, September 2, 2016, FDA issued the long expected final rule for over-the-counter (OTC) consumer antiseptic wash products. As a result, FDA will exclude 19 active ingredients, including Triclosan that have been listed on the previous 1994 tentative final monograph for over-the-counter antiseptic wash products.

In the new ruling, FDA confirms that only products intended for use by the general population either in the home or in certain public settings are included. FDA recognizes the benefit to public health from antiseptic hand washes intended for use in healthcare settings or by professional food handlers and the new ruling **does not affect products used in either of these settings**. FDA will create separate monographs covering these products.

FDA has also confirmed that the new ruling **does not affect products to be used without water, such as Deb InstantFOAM® hand sanitizers**, in any setting. FDA recognizes that such products provide a public health benefit especially when washing with soap and water is not convenient and will address these products also in a separate ruling.

For Consumer Antiseptic Handwashes, FDA has deferred a decision on the future status of three active ingredients, Benzethonium Chloride, PCMX and Benzalkonium Chloride, and has asked the industry to provide additional data for these ingredients. Manufacturers, including Deb Group, have formed working groups to provide the additional data required by the FDA. FDA has initially deferred the final ruling for these ingredients for one year. This deferral is renewable depending upon the satisfactory progress of the work plans to provide data about the safety and efficacy of these ingredients. Benzalkonium Chloride and PCMX are already used as actives in a number of Deb products and these will continue to be available while the required data is provided to FDA.

FDA allows a year grace period to be compliant with the new monograph, after which time it will no longer be possible to supply consumer antiseptic handwashes containing any of the 19 excluded actives. At this time there is no urgent need to replace any product with removed actives including Triclosan, however Deb Group is well advanced in developing new additional antibacterial products based on supported ingredients. These new antibacterial formulations will replace the current formulations with Triclosan and will be available in due time.

