

US Marshals seize sanitizer for bacteria problems

August 2 2009

(AP) -- Officers with the U.S. Marshals Service have seized all skin sanitizers and skin protectants, including ingredients and components, at Clarcon Biological Chemistry Laboratory's facility in Roy, Utah, the Food and Drug Administration said.

The FDA also warned the public Saturday not to use any Clarcon products because they contain <u>harmful bacteria</u> and are promoted as antimicrobial agents that claim to treat open wounds, damaged <u>skin</u>, and protect against various infectious diseases. No cases have been reported to the FDA.

Clarcon voluntarily recalled the affected products, marketed under several different brand names, in June 2009, following an FDA inspection that revealed high levels of potentially disease-causing bacteria in the products.

The inspection also uncovered serious deviations from the FDA's regulations, including poor practices that permitted the contamination. The FDA's seizure of these products, along with their ingredients, occurred after Clarcon did not agree to promptly destroy them. The FDA said it is protecting the public by preventing these products from entering the marketplace.

"The FDA is committed to taking enforcement action against firms that do not manufacture drugs in accordance with our current good manufacturing practice requirements," said Deborah M. Autor, director



of the FDA's Center for <u>Drug Evaluation</u> and Research Office of Compliance.

Clarcon produced and distributed over 800,000 bottles of these products in multiple regions of the country since 2007. Consumers should not use any Clarcon products and should dispose of them in their household trash.

Analyses of several samples of the topical antimicrobial skin <u>sanitizer</u> and skin protectant products revealed high levels of various bacteria. Some of these <u>bacteria</u> can cause opportunistic infections of the skin and underlying tissues. Such infections may need medical or surgical attention and may result in permanent damage, the FDA said.

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