

Hand Sanitizers Carry Unproven Claims to Prevent MRSA Infections

Some hand sanitizers and antiseptic products come with claims that they can prevent MRSA infections.

Don't believe them. These statements are unproven, says the Food and Drug Administration (FDA).

MRSA (methicillin-resistant *Staphylococcus aureus*) is a bacterium that can cause severe—even life-threatening—infections that do not respond to standard treatment with the antibiotic methicillin.

"*Staphylococcus aureus* itself is a very aggressive organism," says Edward Cox, M.D., M.P.H., director of FDA's Office of Antimicrobial Products. "It's often associated with patients in hospitals who have weakened immune systems, but the bacterium can also cause significant skin infections and abscesses in a normal, healthy person. And it can get into the bloodstream and, less frequently, may involve the heart valve, which is very difficult to treat."

But this antibiotic-resistant strain is even more difficult to treat. "With MRSA, a number of the antibiotic drugs we typically used often don't work, so we lose treatment options we used to rely upon," says Cox.

FDA is cracking down on companies that break federal law by promoting their products as preventing MRSA infections and other diseases without agency review and approval.



The claims on the box that this product kills 99.9% of MRSA, staph, and strep—and on the tube that it helps prevent skin infections caused by MRSA—are unproven, according to FDA.

"Consumers are being misled if they think these products you can buy in a drug store or from other places will protect them from a potentially deadly infection," says Deborah Autor, compliance director at

FDA's Center for Drug Evaluation and Research.

FDA wants consumers to watch out for unproven product claims, too—whether they buy a product from a retail store or through the Internet.

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Examples of unproven claims found on product labels are

- kills over 99.9% of MRSA
- helps prevent skin infections caused by MRSA and other germs
- is effective against a broad spectrum of pathogens, including MRSA

One company claims that its hand sanitizing lotion prevents infection from the bacterium *E. coli* and the H1N1 flu virus. And another firm claims its “patented formulation of essential plant oils” kills the bacterium *Salmonella*. These claims are also unproven and, therefore, illegal.

“FDA has not approved any products claiming to prevent infection from MRSA, *E. coli*, *Salmonella*, or H1N1 flu, which a consumer can just walk into a store and buy,” says Autor. “These products give consumers a false sense of protection.”

FDA Warns Companies

On April 20, 2011, FDA issued Warning Letters to four companies that make or distribute the following products that can be bought over-the-counter (without a prescription):

- Staphaseptic First Aid Antiseptic/Pain Relieving Gel, by Tec Laboratories

- Safe4Hours Hand Sanitizing Lotion and Safe4Hours First Aid Antiseptic Skin Protectant, by JD Nelson and Associates
- Dr. Tichenor’s Antiseptic Gel, by Dr. G.H. Tichenor Antiseptic Co.
- Clean Well All-Natural Hand Sanitizer, Clean Well All-Natural Hand Sanitizing Wipes, and Clean Well All-Natural Antibacterial Foaming Hand Soap, by Oh So Clean Inc., also known as Clean-Well Company

If the companies do not correct the violations explained in the Warning Letters within 15 days, FDA may seize the products or take other legal action.

Advice for Consumers

- Don’t buy over-the-counter hand sanitizers or other products that claim to prevent infection from MRSA, *E. coli*, *Salmonella*, flu, or other bacteria or viruses.
- Ask your pharmacist or other health care professional for help in distinguishing between reliable and questionable information on product labels and company websites.
- In general, wash hands often, especially before handling food, to help avoid getting sick. Wash hands with warm water and soap

for 20 seconds. For children, this means the time it takes to sing the “Happy Birthday” song twice.

- If you find products on the Internet that you believe make false or unproven claims, tell FDA by following the instructions at Reporting Unlawful Sales on Internet (www.fda.gov/Safety/ReportaProblem/ucm059315.htm).
- Report side effects that you think may be related to using hand sanitizers or other medical products to FDA’s MedWatch Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.
 - Online (www.fda.gov/Safety/MedWatch)
 - Regular Mail: Use postage-paid, pre-addressed FDA form 3500 (www.accessdata.fda.gov/scripts/medwatch/)
 - Fax: 800-FDA-0178
 - Phone: 800-332-1088

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