**FDA NEWS RELEASE**

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**Media Inquiries**: Shelly Burgess, 301-796-4651; [shelly.burgess@fda.hhs.gov](mailto:shelly.burgess@fda.hhs.gov)  
**Consumer Inquiries**: 888-INFO-FDA

### FDA warns companies to stop making MRSA claims for over-the-counter products

The U.S. Food and Drug Administration issued four 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 also 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.

The FDA warning letters were sent to the following firms:

* Tec Laboratories for Staphaseptic First Aid Antiseptic/Pain Relieving Gel;
* JD Nelson and Associates for Safe4Hours Hand Sanitizing Lotion and Safe4Hours First Aid Antiseptic Skin Protectant;
* Dr. G.H. Tichenor Antiseptic Co. for Dr. Tichenor’s Antiseptic Gel;
* Oh So Clean, Inc dba CleanWell Company for CleanWell All-Natural Foaming Hand Sanitizer, CleanWell All-Natural Hand Sanitizer, CleanWell All-Natural Hand Sanitizing Wipes, and CleanWell All-Natural Antibacterial Foaming Handsoap

The warning letters explain that the companies are marketing these products in violation of federal law.

“MRSA is a serious public health threat,” said Deborah Autor, director of the Office of Compliance in the FDA’s Center for Drug Evaluation and Research. “The FDA cannot allow companies to mislead consumers by making unproven prevention claims.”

The companies have 15 days to correct the violations cited in the warning letters. Failure to do so may result in legal action including seizure and injunction.

Health care professionals and patients are encouraged to report adverse events or side-effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

* Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
* [Download form](https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Consumers that have purchased these products should contact their physicians if they suspect a skin infection is either worsening or not improving.

Warning Letter information:

[Tec Laboratories](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm251975.htm)

[JD Nelson And Associates](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm252038.htm)

[Dr G.H. Tichenor Antiseptic Company](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm251938.htm)

[Oh So Clean, Inc](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm251979.htm)

[Related Consumer Update](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm251816.htm)

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