# FDA Wants Label, Packaging Changes To Reduce Infection Risk Involving Topical Antiseptics

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The FDA wants label and packaging changes for certain topical antiseptic products to reduce the risk of infection.

The agency said on Wednesday that it is evaluating "infrequent but continuing reports of infections resulting from antiseptic products [1] labeled for preoperative or preinjection skin preparation."

The risk of infection apparently arises most often from user contamination; however, contamination can also occur during the manufacturing process [2], as topical antiseptics are not required to be manufactured as sterile.

The FDA has recommended that these products -- available as single- or multiple-use -- be sold only as single-use preparations. In addition, the antiseptics should not be diluted after opening and any leftover solution should be discarded.

The FDA also has requested that manufacturers voluntarily revise the product labels for topical antiseptics to indicate whether the drug is manufactured as a sterile or nonsterile product. However, it cautioned that even products manufactured as sterile can become contaminated during use and that the term "nonsterile" does not mean the product contains harmful bacteria.

Last year, manufacturers, clinicians, and policy analysts told the FDA at a public hearing that requiring these products to be sterile [3] would not dramatically reduce the rate of infection -- but it would raise the cost of these products.

Continue reading... [4]



**Links:**
[1] http://www.fda.gov/Drugs/DrugSafety/ucm374711.htm
[2] http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/27075
[3] http://www.medpagetoday.com/Washington-Watch/FDAGeneral/36448
[4] http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/42915