8.0 Common claims on professional use of antiseptics

We suggest the agency's stance on claims be more clearly stated. There are a variety of claims that are commonly made on professional use topical antiseptic products that do not have clear definition or an understanding of what data would be needed to support such claims. This variability makes if difficult for an end user to compare products and accurately determine what product will meet the desired needs. Example literature is provided in Attachment B that demonstrates the wide variation in labeling and claims throughout the industry. Some example of commonly used claims made on topical antiseptic products include:

8.1 Virucidal

We suggest the agency's stance on anti-viral claims be more clearly stated. It is our understanding that the FDA will not permit broad-spectrum anti-viral claims because testing on a limited number of viruses, unlike bacteria, cannot predict the effect upon untested viruses based on the comments below. Many germicides will work on many viruses, but be ineffective upon another very similar virus. In order to make a claim FDA and EPA require testing each virus individually, and there are over 150-200 viruses that affect humans. Some authorities do recognize viral claims based on the classification of Klein and De Forest [10,11] of a very large number of exceptions, neither the FDA nor EPA recognize broad spectrum anti-viral activity (Fed. Reg.1975). However, the claim of virucidal is in common use and appears upon many labels of products marketed under the monograph.

8.2 Sporicidal and fungicidal

Although not specifically addressed in the TFM, we suggest that the word "spores" be specifically addressed to avoid confusing wording such as "kills anthrax" or "kills spore forming bacteria", without specifically specifying sporicidal (spore kill) or sporistatic (spore inhibition) activity data.

In the case of spore forming bacteria such as *Bacillus anthracis* (anthrax) and *Clostridium difficile,* a distinction should be made between the bacteria's vegetative cells and the bacterial spores. While the bacteria's vegetative cell is very susceptible to most antimicrobials, the spores are very hardy and resistant to antimicrobials. Any broad spectrum topical antimicrobial agent should readily kill the vegetative cells in a test tube, or on the surface of the skin, but because some bacteria germinate and multiply within living tissue (e.g. anthrax) topically applied antimicrobial will not be able to reach the bacteria. Several studies have demonstrated that ethyl alcohol has little killing effect against bacterial spores.

8.3 Effective against antibiotic resistant organisms

This is an important issue for the healthcare professional. Due to unstated requirements for this labeling claim, healthcare professionals may be mislead. The FDA needs to provide clear requirements of what testing is required to substantiate these claims regarding the effectiveness against antibiotic resistant organisms.

8.4 For use as a re-entry product

3M has become aware of a number of alcohol only products that claim that they can be used as a "re-entry" or "interim" product for hand antisepsis prior to surgery. The agency should clarify that products sold for surgical hand scrubbing must meet the requirements stated in 333.414 and no sub-category of "re-entry to the operating room" with lower performance criteria exists.

8.5 Chlorhexidine Gluconate (CHG) compatible

This claim is routinely found in antiseptic products. However the TFM does not provide testing requirements that would substantiate this claim. The FDA should provide clarity on what testing is required to substantiate a claim of CHG compatibility.