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ALCOHOL WITH DISINFECTANT AND ANTISEPTIC ACTIONS

The Bureau of Food and Drugs for purposes of clarification, rule making and regulatory action is issuing the following statements regarding the advertising and promotional claims of makers of 70% ethyl or isopropyl alcohol. Prior to the issuance, definition of terms is necessary.

- 1. Disinfectant refers to a chemical agent which destroys microorganisms; it does not necessarily kill all microorganisms, but renders them to be non harmful to health or quality of perishable goods. This term applies to agents used to treat inanimate objects and materials and may also be used topically to treat the skin and other body membranes and cavities. Example of these are 70% ethyl or isopropyl alcohol, chlorhexidine.
- 2. Antiseptic refers to chemical agent which destroys or inhibits microorganisms on living tissues with the result of limiting or preventing the harmful effects of infection. Examples of these are: Povidone Iodine, Benzalkonium chloride, Cetrimide etc.
- 3. Sterilization means the total removal or destruction of all living microorganisms.
- 4. Sterilizers refer to agents which cause sterilization. Examples of these are: chemical agent ethylene chloride and gamma irradiation.
- 5. Preservatives refer to agents which prevent microbial spoilage of preparations.

Rubbing alcohol should contain 68.5 - 71.5% by volume of absolute ethyl/isopropyl alcohol. Its uses include disinfectant for skin (prior to injection and venipuncture), as solvent and as pharmaceutical preservative. Although alcohol is a bactericidal antiseptic and disinfectant, it is ineffective against bacterial spores like Clostridium tetani, welchii and Bacillus anthracis. Hence, alcohol should not be used for disinfection/sterilization of surgical and dental instruments. Also, alcohol is not considered suitable for disinfecting surfaces and materials especially contaminated by blood and other body fluids because of its limited penetration of organic residue and rapid evaporization.

For the guidance of all those concerned, the claim of sterilizing activity of alcohol is not acceptable based on above evidences. Any product using the claim "sterilizing", in order to put an appearance of advantage over another alcohol product, is considered violative and should be answerable to sanctions that are to be enforced by BFAD.