Tipsheet for DSP Production of Hand Sanitizer

YOU MUST

- Register with the FDA - There are no exceptions to this requirement in the guidance. You will be making an OTC drug.
- When manufacturing hand sanitizer, the ethanol used must be denatured, whether manufactured or purchased. There are no exceptions in the guidance. FDA feels strongly this is a safety issue.
- Label according to Appendices A-D depending on application (Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products…):
    - Include a batch number
    - Include company name and contact info (if labels without this information are already ordered or printed, FDA does not intend to take actions against manufacturers for this)
- Make the ethanol that is the Active Pharmaceutical Ingredient (API) in hand sanitizer using the same fermentation and distillation processes used for consumable goods. Alcohol from synthetic processes is used only if it meets USP or FCC grade.
- Label the ethanol API as either denatured or undenatured as shown in Appendix A and B of the applicable guidance (Temporary Policy for Manufacture of Alcohol for Incorporation Into…).
- Keep a record of key steps and controls for batches.
- Verify and document the final alcohol content of sanitizer using the best methods available at the manufacturer (WHO guidance tolerance 75%-85% abv for ethanol).
- Create an adverse event reporting process.

YOU MAY

- Denature the ethanol according to:
    - 40-B *denatonium benzoate, N.F. with or without tert-butyl alcohol*
    - 40-A *sucrose octaacetate with or without tert-butyl alcohol*
    - 3-C *isopropyl alcohol*
    - Other formulas should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov
- Make the ethanol used as an API with lower alcohol content than 94.9% abv, so long as it is labeled accordingly, and finished hand sanitizer meets the ethanol volume to content concentration of 80%.
- Use glycerin or glycerol that is USP or FCC, aka “food grade.”
- Use Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP. Technical grade falls within this policy if the concentration is within that of the USP versions.

- Put a manufacturing date (such that manufacturing is shown to have taken place during the Public Health Emergency).
- Send alcohol API in a denatured or undenatured form to qualified firms for production into and sanitizers.

DO NOT

- Add other ingredients than specified.
- Make sanitizer using undenatured ethanol. The TTB guidance now matches FDA guidance, and the FDA considers this a safety issue.