OBSERVATION 1

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. For example,

a) Your firm uses (b) (4) water in certain drug products whose formulation requires water. Your firm is also using the (b) (4) water to make (b) (4) Water (b) (4) for use in certain drug products. Your firm has no documentation of any testing performed (analytical or microbiological) to show the water at least at minimum meets the specifications for Purified Water, USP. Examples of products made using the (b) (4) water include lot #09082017@10 of Clonidine (Grape Simple Syrup) 0.1mg/mL Suspension and lot #11012017@21 of Clonidine (Strawberry/Marshmallow Simple Syrup) 0.1 mg/mL Suspension. Examples of lots made using the (b) (4) Water made from the (b) (4) water include lot #11302017@33 of Tranexamic Acid 5% Solution and lot #11212017@32 of Dexamethasone/Gentamicin/Itraconazole 0.1%/80mg/100mg/30mL Nasal Spray.

b) Your firm uses Acetone CP grade for making drug products. The Acetone is labeled for “technical use only”. In the past 6 months, your firm made (b) (4) of drug product using the Acetone CP - lot #10062017@10 of Squaric Acid (In Acetone) 0.1% Solution.