OBSERVATION 1

Your firm used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, production personnel use (b) (4) [redacted] to produce all non-sterile oral solutions and suspensions which contain (b) (4) [redacted]. Your firm does not assess microbial or (b) (4) [redacted] of (b) (4) [redacted]. Production personnel used (b) (4) [redacted], lot (b) (4) [redacted], to produce more than 50 finished products including Miracle Mouthwash, lot 07092019@146; and Potassium Bromide, lot 07192019@153.