1. Non-microbial contamination was observed in your production area. Specifically,

On 08/29/2018, I conducted a walk-through of the clean rooms used for compounding hazardous and non-hazardous sterile drugs. I observed white fiber-like particles on the surface of the [redacted] located in the hazardous clean room. This ISO 5 area is used in the production of sterile hazardous drug products.

2. The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

Your firm is not aware of the concentration of the sporicidal agent used, [redacted], and lacks assurance that the concentration applied to ISO 5 surfaces is adequate for use as a sporicidal agent.

3. You used a non-pharmaceutical grade component in the formulation of a drug product. Specifically,

[redacted] is used as an ingredient in non-sterile compounded drug products, such as Sodium Butyrate Enema 11.01mg/ml solution, Naltrexone 4mg/ml suspension, and Methocel (Potassium Sorbate) 2% Gel. Your firm does not monitor the [redacted] nor conduct microbial and/or chemical analysis to ensure it meets USP standards.