DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 1**

Procedures designed to identify and prevent insanitary conditions are not established and followed by your firm.

Specifically,

Your firm did not perform appropriate environmental monitoring in your aseptic processing areas. For example, pressure differentials between areas with different air classifications were not monitored before or during sterile drug production.

The air pressure differential between the ISO 5 (b)(4) and the ISO 7 clean room is not monitored. Instead personnel perform a (b)(4) visual inspection of the pressures on the (b)(4) and the clean room gauge, and record the pressures on the Cleaning and Calibration Log. Additionally, there is no pressure gauge to monitor the pressure or pressure differential between the ISO 7 clean room and the uncontrolled environment in the vestibule.

This is a repeat observation from the 2017 inspection.