DURING AN INSPECTION OF YOUR FIRM (I) Observed:

OBSERVATION 1

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, the firm compounds sterile drug products which involves several aseptic manipulation steps. The firm's sterile drug product batch size can range up to (b)(4) for the sterile drug product Cyclosporine 1%. The current media fills are performed only with (b)(4) .

OBSERVATION 2

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically, there is no verification of the pressure differentials before or during sterile drug production. Pressure differentials are measured with (b)(4) which are not visible from within the cleanroom. The firm has no alarm system that would signal if room pressures were out of specification. Pressure differential values are only recorded (b)(4) .
OBSERVATION 3

Non-microbial contamination was observed in your non-sterile drug production area.

Specifically, on 07/13/2021, we observed what appeared to be drug product residue on two ceiling light fixtures in the firm’s non-sterile compounding area. These light fixtures were directly above the firm’s non-sterile benchtop drug product staging areas. The firm was continuously processing non-sterile drug products in this area during this inspection. On 07/16/2021, we observed that this residue was still on the light fixtures.
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."