DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1
You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, the cleaning of hazardous drug product is not adequate. Your firm’s cleaning between compounded products included only a wipe down of the compounding area/compounding hood with (b)(4). Your firm could not provide evidence that (b)(4) cleaned the hazardous drugs compounded at your firm. Additionally, you could provide no evidence that the detergents used to wash utensils and equipment remove the hazardous drug products you work with. The compounding area/compounding hood, utensils, and equipment are shared amongst all products (both hazardous drugs and non-hazardous drugs) at your pharmacy. Hazardous drugs compounded at your firm include Chloramphenicol, Methimazole, Diethylstilbestrol, Leflunomide, Estradiol, Apomorphine, Tretinoin, Oxytocin, Fluconazole, and Finasteride.

Your firm did not provide adequate cleaning of the (b)(4) hoods used to compound all hazardous drugs and non-hazardous drugs with (b)(4) ingredients. On 8/26/2019, I observed particle build up on the wires and the power strip located in the back of hood serial number (b)(4). The wires and power strip are kept less than a foot from areas with open containers during compounding. On 8/26/2019, the balance in hood serial number (b)(4), which used to weigh (b)(4) ingredients for compounding, had a buildup of material. These items were not removed during that day of compounding.

OBSERVATION 2
You used a non-pharmaceutical grade component in the formulation of a drug product.
Specifically,
Your firm used an expired ingredient to compound several topical prescriptions. Vitamin A Palmitate in Almond Oil lot (b) (4) expired on 01/01/19. Additionally, this lot of Vitamin A’s label indicates that it should be stored refrigerated. The Vitamin A was held at room temperature. This Vitamin A was used in the compounding of 21 prescription products in the last three months.

*DATES OF INSPECTION