DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1:
Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, non-sterile drug preparations both oral and topical use (b) (4) and (b) (4) water rather than a purified USP grade water. Examples of these include:

A. Magic mouthwash #50 (b) (4) lot A0913C19
B. HQ 4% REG HC Pump (b) (4) lot E1517C9

Observation 2:
Hazardous and highly potent drugs were prepared and handled without providing adequate cleaning of work surfaces and reusable equipment such as spatulas, (b) (4), and the (b) (4) (b) (4) to prevent cross-contamination.
Specifically, your operations include the preparation of non-sterile drug products that contain anti-neoplastic agents such as fluorouracil and hormones such as estriol using reusable equipment that was (b)(4) cleaned using (b)(4) water, (b)(4) and (b)(4). Working surfaces are wiped down using (b)(4). You do not have documentation to show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations are as follows:

A. The fluorouracil lot (b)(4) bulk drug substance was used to prepare 5-fluorouracil 5%/HC 1% cream lot 0716C13.

B. The estriol lot (b)(4) bulk drug substance was used to prepare estriol 1mg/gm VC cream lot E0517C10.

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