Assessment of Risk for USP <800> Compliant Alternative Containment Strategy

Drug Name: Testosterone	**Assessment of Risk Completed on (Date):** 6/26/19

Type of HD

☐Antineoplastic
☒Non-antineoplastic (may pose a reproductive risk)
☐Reproductive risk primarily

Dosage Form

☐Tablet of conventionally manufactured product that requires only packaging or counting
☐Capsule of conventionally manufactured product that requires only packaging or counting
☐Oral liquids of conventionally manufactured product that requires only packaging or counting
☐Injectables of conventionally manufactured product that requires only packaging or counting
☒Other (explain): Bulk Powder API

Packaging - *Include drug name, strength, and dosage form.*

Testosterone 50 mg/ml cream

Risk of Exposure

☐ **NIOSH Table 1:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Many of these drugs are cytotoxic and may also be hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

Supplemental Information:
Route of exposure: Contact with skin (injectables, repackaged oral liquids)
Ingestion of HD materials (capsules)
Inhalation (powder)

☐ **NIOSH Table 2:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

Supplemental Information:
Route of exposure: Contact with skin (injectables, repackaged oral liquids)
Ingestion of HD materials (capsules)
Inhalation (powder)

☒**NIOSH Table 3:** Potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.

Supplemental Information: Children should avoid contact with unwashed or unclothed application sites on skin; FDA pregnancy category X
Route of exposure: Contact with skin (injectables, repackaged oral liquids)
Ingestion of HD materials (Capsules)
Inhalation (Powder)

Alternative Containment Strategies

- The receipt of any HD, except for an antineoplastic or API, will be handled and stored per the manufacturer.
- HD tablets and capsules will be cut, crushed, or otherwise manipulated ONLY in a C-PEC work station (double HEPA or vented to the outside) with a powder shield to protect the worker's face and eyes from exposure.
- Protection of face (with face shields), eyes (with goggles), and skin (with gloves) when manipulating HD liquids.
- The final compounded HD product will be placed in a sealed impervious plastic bag and labeled as per protocol.
- Non-disposable materials used to compound the HD will be cleaned in an empty sink with a specified lab grade detergent and suitable cleaning process as determined by protocol.
- The materials, sink, and designated compounding area will be decontaminated per protocol or material data sheet.
- Plastic wrap, PPE, and cleaning materials will be placed in hazardous waste disposal located near the compounding area, if necessary per HD disposal protocol.

Based on Assessment of Risk our pharmacy will proceed as follows:

☒Follow alternative containment strategies documented above
☐Follow all USP <800> requirements

Assessment of Risk written by:

_____ Date: 6/26/2019

Reviewed by Pharmacy Manager:

_____ Date: 6/26/2019

*Disclaimer: This assessment of risk is a baseline template and may need to be individualized for different drug products per USP <800> standards as required by your State. The information contained in this template is not intended to constitute legal advice, nor serve as a substitute for the engagement of qualified professionals.