DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	8/24/2015-8/28/2015
	FEI NUMBER 3011752429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William O. Richardson , Chief Executive Officer

FIRM NAME	STREET ADDRESS
Isomeric Pharmacy Solution, LLC	2401 S Foothill Dr, Suite D
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84109-1479	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

A. Your firm has not validated the terminal sterilization process of the moist heat autoclave to demonstrate a heat penetration of 121 degrees Celsius in the Triamcinolone Acetonide/Lidocaine HCL 40/10 mg/mL Injectable suspension drug vial.

B. Your firm has not qualified the Tuttenaeur Autoclave (Equip #EQ-0013, Model #EZ10 2540EA, Serial #14120302) that was used to terminally sterilize compounded product Triamcinolone Acetonide/ Lidocaine HCL 40/10 mg/mL Injectable Suspension, Lot Number: 06302015@4, on June 30th, 2015. Specifically, your operational qualification did not include calibration of the autoclave's pressure and time parameters. In addition, a performance qualification of simulated real world autoclave conditions has not been completed.

C. Your firm's in situ air pattern analysis (smoke studies) was not conducted under dynamic conditions, simulating routine production (I.e. compounding equipment in place and operations ongoing). Without, there is no assurance critical processing areas are suitable for aseptic manufacturing of sterile drug products. The three current smoke study videos (for each of the three laminar flow hoods) were filmed on May 13th, 2015.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Erika V Butler, Investigator Zachery L Miller, Investigator X Erika V Butler Erika V Butler Investigator Signed by: Erika V. Butler-S	8/28/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	8/24/2015-8/28/2015
	FEI NUMBER 3011752429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William O. Richardson , Chief Executive Officer	
FIRM NAME Isomeric Pharmacy Solution, LLC	STREET ADDRESS 2401 S Foothill Dr, Suite D
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84109-1479	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically,
A. Your firm does not conduct viable and non-viable air sampling (environmental monitoring) in your ISO 5 laminar flow hoods during compounding operations. For example, viable and non-viable monitoring was not performed during the compounding of Triamcinolone Acetonide/Lidocaine HCL 40/10 mg/mL Injectable Suspension, Lot Number: 06302015@4 .

B. There is no scientific justification or documentation for the sampling locations of the affixed active air particle counters located in the ISO 7 compounding suites. One particle counter is located on the wall behind the ISO-5 laminar flow hood away from the activity in the cleanroom. The other is located on the viewing glass wall approximately 10 feet away from the biological safety cabinet.

OBSERVATION 3
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,
Your firm has not conducted a stability study to support the beyond use dating of 90 days for Triamcinolone Acetonide/Lidocaine HCL 40/10 mg/mL Injectable suspension drug.

OBSERVATION 4
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,
Your firm does not test the preservative content of Benzyl alcohol and sodium chloride utilized as preservatives in the formulation for Triamcinolone Acetonide/Lidocaine HCL 40/10 mg/mL suspension at time of release.

OBSERVATION 5

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Erika V Butler, Investigator Zachery L Miller, Investigator X Erika V Butler 8/28/2015 Erika V Butler Investigator Signed by: Erika V. Butler -S	8/28/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	8/24/2015-8/28/2015
	FEI NUMBER 3011752429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William O. Richardson , Chief Executive Officer	
FIRM NAME Isomeric Pharmacy Solution, LLC	STREET ADDRESS 2401 S Foothill Dr, Suite D
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84109-1479	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

The labels of your outsourcing facility's drug products do not include information required by sections 503B(a)(10)(A) and (B).

Specifically, the following information is not found on your drug product labels:

- The statements, "This is a compounded drug" and "Office Use Only."

Examples of drug product labels that do not contain this information:

  - Triamcinolone Acetonide/Lidocaine HCl 40/10 mg/mL Injectable Suspension
  - Betamethasone Acetate/Betamethasone Sodium Phosphate 3/4 mg/mL Injectable Suspension
  - Cyanocobalamin/Methionine/Inositol/Choline Chloride 1/25/50/50 mg/mL Injection

- The statements, "This is a compounded drug" and "Not for Resale," storage and handling instructions, and the date the drug was compounded.

Examples of drug product labels that do not contain this information:

  - Progesterone Capsule E4M150 mg
  - Cyclobenzaprine/Diclofenac/Gabapentin/Ketamine/Orphenadrine/ Tetracaine 2%/3%/10%/15%/5%/2% 40 GM
  - Liothyronine/Levothyroxine 20 mcg/75 mcg Capsules

Furthermore, the following information is not found on the container labels for some drug products you produce:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	8/24/2015-8/28/2015
	FEI NUMBER 3011752429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William O. Richardson , Chief Executive Officer	
FIRM NAME Isomeric Pharmacy Solution, LLC	STREET ADDRESS 2401 S Foothill Dr, Suite D
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84109-1479	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

- The route of administration.

Examples of container labels that do not contain this information:

- Triamcinolone Acetonide/Lidocaine HCl 40/10 mg/mL Injectable Suspension
- Betamethasone Acetate/Betamethasone Sodium Phosphate 3/4 mg/mL Injectable Suspension
- Cyclobenzaprine/Diclofenac/Gabapentin/Ketamine/Orphenadrine/ Tetracaine 2%/3%/10%/15%/5%/2% 40 GM

- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of container labels that do not contain this information:

- Progesterone Capsule E4M150 mg
- Cyclobenzaprine/Diclofenac/Gabapentin/Ketamine/Orphenadrine/ Tetracaine 2%/3%/10%/15%/5%/2% 40 GM
- Liothyronine/Levothyroxine 20 mcg/75 mcg Capsules

8/28/2015

X Zachery L Miller

Zachery L Miller
Investigator
Signed by: Zachery L. Miller -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Erika V Butler, Investigator Zachery L Miller, Investigator	8/28/2015 X Erika V Butler Erika V Butler Investigator Signed by: Erika V. Butler -S	DATE ISSUED 8/28/2015