

September 17, 2015



William Richardson  
(800) 418-0730  
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will@isomericrx.com

A handwritten signature in black ink, appearing to be 'WR', located below the contact information.

LaTonya Mitchell  
6th & Kipling Street  
Building 20  
Denver, CO 80225

**Re: Isomeric Pharmacy's WAIVER for Publication of Response to FDA Form 483 Issued August 28, 2015; FEI No. 3011752429**

Dear Ms Mitchell,

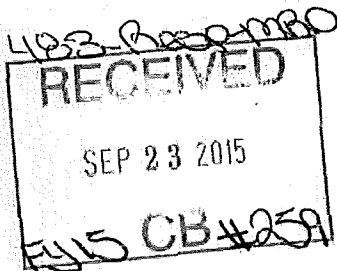
On behalf of Isomeric Pharmacy Solutions (Isomeric), my signature hereby authorizes the United States Food and Drug Administration to publicly disclose the information described below on FDA's website. I understand the information that is disclosed may contain confidential information or trade secrets within the meaning of U.S.C. §1905, 21 U.S.C. §331 (0), and 5 U.S.C. §552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations.

Information to be disclosed: Isomeric's September 17, 2015 Response to FDA Form 483 Issued August 28, 2015; FEI No. 3011752429 dated, excluding attachments/exhibits, which responds to FDA's Form 483 dated September 17, 2015.

Sincerely,

A handwritten signature in black ink, appearing to be 'WR', located below the word 'Sincerely,'.

William Richardson  
CEO  
Isomeric Pharmacy Solutions



**Isomeric Pharmacy Solutions**

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LaTonya Mitchell  
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**Re: Isomeric Pharmacy's Response to FDA Form 483 Issued August 28, 2015; FEI No. 3011752429**

Dear Ms Mitchell,

On behalf of Isomeric Pharmacy Solutions ("Isomeric"), located in Salt Lake City, Utah, I am William Richardson, CEO of Isomeric Pharmacy Solutions. Please allow this letter to serve as our response to the Federal Food and Drug Administration's ("FDA") Denver Colorado Office, inspection of Isomeric which occurred August 24, 25, 26, 27, and 28, 2015. At the conclusion of the inspection, FDA Investigators, Erika Butler and Zachary Miller, conducted a close-out meeting and presented an FDA form 483, listing five Observations. Isomeric's response to the FDA form 483 is outlined below.

### **Introduction**

Isomeric is an Outsourcing and Sterile Compounding Pharmacy licensed by the State of Utah. Isomeric places patient safety at the top of its priorities and strives to provide the best in customer service. Isomeric is a state of the art facility utilizing new technologies to ensure that quality products are consistently produced.

Isomeric is committed to achieving and maintaining all current Good Manufacturing Practices in its operations. Isomeric thanks the FDA and its Investigators in helping Isomeric achieve its goal of safely serving the public and providing the highest quality products.

## **OBSERVATION 1**

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

***Investigator Comments 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.*

**Isomeric's Response A:**

Isomeric will conduct new validation studies of the terminal validation process of the moist heat autoclave to demonstrate consistent heat penetration of 121 degrees Celsius into the injectable suspension drug vial.

**Completion Date: October 9, 2015**

**See attached Schedule "A" & "B" for supporting documentation**

***Investigator Comments B:***

*Your firm has not qualified the Tuttenaur 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.*

**Isomeric's Response B:**

Isomeric will operationally qualify the calibration of the pressure and time parameters of the Tuttenaur autoclave. In addition it will complete a performance qualification of simulated real world autoclave conditions.

**Completion Date: October 9, 2015**

**See schedule "B" for validation documentation**

**Investigator Comments 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.*

**Isomeric's Response C:**

Isomeric has conducted an in situ air pattern analysis (smoke studies) in all three of the ISO-5 laminar flow hoods under dynamic conditions, which included all equipment, vials, supplies and other items to simulate routine production and ensure that these critical processing areas are suitable for aseptic manufacturing of sterile drug products. These were completed on Sept. 2, 2015.

**Completion Date:**

**September 2, 2015**

See schedule "C" for video

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**Observation 2**

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

**Investigator Comments 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.*

**Isomeric's Response A:**

Isomeric has updated its environmental monitoring policies and procedures to now include viable and non viable air samplings in its ISO 5 laminar flow hoods during all compounding operations.

**Completion Date:**

**September 18, 2015**

See Schedule "D" for validation documentation.

**Investigator Comments 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.*

**Isomeric's Response B:**

Isomeric is installing additional air particle counters within one foot of each of the ISO 5 environments as well as re-locating the particle counter that is behind the ISO 5 laminar flow hood. All particle counters will be taking samples of each hood every minute, 24 hours per day, 7 days a week.

**Completion Date:** October 31, 2015

See Schedule "E" for validation documentation.

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**Observation 3**

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

***Investigator Comments:***

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

**Isomeric's Response:**

Isomeric has now implemented a written testing program designed to assess the stability characteristics of drug products. This program includes a cGMP validated stability study to accompany all beyond use dates.

**Completion Date:** September 7, 2015

See schedule "F" for validation documentation.

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**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.**

**Investigator Comments:**

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

**Isomeric's Response:**

Isomeric has now implemented a process to ensure testing and release of drug products for distribution, to include the appropriate process to ensure laboratory determination of satisfactory conformance to the final specifications prior to release. This includes the testing of 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.

**Completion Date:** September 7, 2015

See schedule "G" for validation documentation

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**Observation 5**

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

***Investigator Comments Part 1:***

*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 Acetone/Lidocaine HCl 40/10 mg/mL Injectable Suspension,*
- *Betamethasone Acetate/Betamethasone Sodium Phosphate 3/4 mg/mL Inejctable 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 E4M 150mg*
- *Cyclobenzaprine/Diclofenac/Gabapentin/Ketamine/Orphenadrine/Tetracaine 2%/3%/10%/15%/5%/2% 40 GM*
- *Liothyronine/Levothyroxine 20 mcg/75 mcg Capsules.*

**Isomeric's Response:**

Isomeric's labels for the outsourcing facility's drug products now include information required by sections 503B(a)(10)(A) and (B).

Specifically all drug product labels now contain the statements:

- For sterile drugs, "This is a compounded drug" and "Office Use Only."
- For non-sterile, patient specific drugs, "This is a compounded drug" and "Not for Resale," - and includes storage and handling instructions and the date the drug was compounded.

**Completion Date:** September 7, 2015

See schedule "H" for validation documentation.

**Investigator Comments Part 2:**

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

*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%/15%/2% 40 GM*

*Information to facilitate adverse event reporting: [www.fda.gov/medwatch](http://www.fda.gov/medwatch) and 1-800-FDA-1088.*

*Examples of container labels that do not contain this information:*

- *Progesterone Capsule E4M 150mg,*
- *Cyclobenzaprine/Diclofenac/Gabapentin/Ketamine/Orphenadrine/Tetracaine 2%/3%/10%/15%/5%/2% 40 GM*
- *Liothyronine/Levothyroxine 20 mcg/75 mcg Capsules.*

**Isomeric's Response:**

Isomeric container labels now include the following:

- Route of administration
- Information to facilitate adverse event reporting: [www.fda.gov/medwatch](http://www.fda.gov/medwatch) and 1-800-FDA-1088

**Completion Date:** September 7, 2015

See schedule "H" for validation documentation.