DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	8/20/2018-10/24/2018* FEI NUMBER 3012315020

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jeremy S. Delk, CEO/Owner	
FIRM NAME	STREET ADDRESS
Tailor Made Compounding, LLC	200 Moore Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Nicholasville, KY 40356-8512	Producer of Sterile Drugs

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

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically, your firm has documented 5 sterility failures since January 2016 to present. The following products were not dispensed to patients:

Date Compounded	Product	Lot Number	Sterility Failure Date
11/1/17	Thymosin Alpha	1101201705	11/15/17
10/30/17	IGF-1	10301704	11/15/17
12/20/17	IGF-1 LR3	12201709	1/10/18
1/24/18	BPC-157	01241805	2/13/18
1/24/18	HCG-4000	01241804	2/13/18

Your firm does not evaluate other products that were produced in the same time-period in which the sterility failure occurred. Per firm management, your firm performs a cleaning after a sterility failure, however, there is no written documentation that this additional cleaning of your ISO 5 and ISO 7 areas is performed.

AMENDMENT 2

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	Michael P Sheehan, Investigator Nicholas L Paulin, Investigator	X Nicholas L Paulin Investigator Signed By: Nicholas L. Paulin -S Date Signed: 10-24-2018 12:52:36	10/24/2018

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

a.) Your firm does not have any hold time studies for how long stoppers, vials and seals (caps) can be stored after being (b) (4) prior to being used in sterile operations. On 8/21/18, we observed your pharmacy technician using the (b) (4) in sterile operations while producing Thymosin Beta Injectable (lot# 0821201806), by (b) (4) with their gloved hands.

b.) Media fills do not simulate your sterile operations process under normal operating conditions. Your media fills are not performed under worst case aseptic processing conditions, for example, your firm produces batches that consists of (b) (4) of vials during normal sterile operations under the ISO 5 hood, whereas your media fill consists of only (b) (4) vials being filled and does not incorporate any interventions that may occur during sterile operations.

c.) Your firm does not include the (b) (4) into the media fill program. No media fills are performed on the (b) (4) process. For example, your firm produces the following two (b) (4) products at your facility: Tesamorelin and HCG.

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, on 8/21/18, while observing sterile operations, we observed a pharmacy technician enter the ISO 7 room, which your firm identifies as the USP 797 room. This room contains the ISO 5 hood. We observed your pharmacy technician enter your USP 797 room from your ISO 7 Ante room with

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ungloved hands (exposed skin). The Ante room is where the technician gowns and washes hands. Upon entering the USP 797 room, we observed the technician immediately apply(b) (4) to his ungloved hands. He then put on sterile gloves.

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

a.) Specifically, smoke studies are conducted every (b) (4) by a third-party. Your firm's smoke studies were performed on (b) (4). Prior to November 2017 your firm did not perform smoke studies. Your firm does not perform smoke studies under dynamic conditions. We reviewed your firm's smoke studies and they were brief and had no description of what action was being performed. Furthermore, while viewing these smoke studies, it was difficult to see smoke on various occasions.

b.) Also, your firm does not include the (b) (4) process in your smoke studies. Your firm (b) (4) two products, Tesamorelin and HCG using a (b) (4) located inside the ISO 5 hood. The process includes (b) (4) vial, (b) (4) vials from the (b) (4) and (b) (4) vial (b) (4) from the (b) (4)

Your smoke studies are performed under static conditions and do not incorporate the(b) (4) process nor any dynamic conditions to evaluate the efficiency of your HEPA airflow.

OBSERVATION 5

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Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm's bactericidal agent (b) (4) used for cleaning is not sterile. Your firm uses (b) (4) for cleaning the ISO 5 hood, ISO 7 rooms and ISO 8 rooms.

OBSERVATION 6

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

a.) Specifically, your firm only conducts personnel monitoring every (b) (4) on each individual that performs sterile operations. No other personnel monitoring is performed besides this (b) (4) monitoring. Your firm does not document the time when personnel monitoring is performed (i.e. before sterile operations, during sterile operations or after sterile operations). Your firm's personnel monitoring consists of finger tips only. No other areas such as forehead, mask, or chest are monitored for the operators.

b.) Your firm does not have alarms connected to your magnehelic gauges to monitor pressure differentials during production. Furthermore, your firm only records the room pressures in the aseptic processing areas (b) (4) and does not monitor the magnehelic gauges during production.

OBSERVATION 7

Labeling materials issued for a batch were not carefully examined for identity and conformity to the labeling specified in the master or batch production records.

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Specifically, on 9/11/18, we observed (b) (4) vials of Tesamorelin 1 mg subcutaneous injection (batch 07161804; BUD Date 07/19) stored in the refrigerator in your pharmacy. The Beyond Use Date (BUD) on each of the (b) (4) Tesamorelin vial labels of this lot contained an incorrect one-year BUD date, while the correct BUD date for Tesamorelin is 180 days.

Your firm began using a new computer program called (b) (4) (b) (4)) on or about 7/6/18 for printing labels to be affixed to finished product vials. When this issue was brought to your management's attention, your firm conducted an investigation which identified that any Tesamorelin product produced and shipped between 7/6/18 to 9/11/18 contains the incorrect one year BUD date, due to an installation error of the new computer program.

Furthermore, these labels are reviewed by a pharmacist prior to releasing the product and this incorrect BUD date on the vial label and/or computer system for Tesamorelin 1 mg subcutaneous injection was not observed. As a result of the investigation, your firm initiated a voluntary recall in September 2018.

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm performs potency testing at various random intervals on products produced. However, there is no set schedule or frequency for when potency testing will be performed. Your firm's specification for potency is (b) (4)% to (b) (4)%. Your firm released 3 products to patients with Out-of-Specification (OOS) potency results.

Product	Lot Number	BUD Date	Sterile/ Non-Sterile	Date Produced	Test Date	Test Result	Released to patients

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Glutathione 200mg Injection	12191702	90 Days	Sterile	12/19/17	1/10/18 2/12/18	92.5% 88.0%	Yes (b)(4) patient
DHEA 75 mg capsules	09081701	180 Days	Non-Sterile	9/8/17	9/20/17	86.1%	Yes (b)(4) patients
Alprostadil/Paparerine/Phentolamine Injection 60mcg, 30 mg, 3 mg	11141713	60 Days	Sterile	11/14/17	11/27/17 12/26/17	95.2% 83.2%	Yes (b)(4) patient

OBSERVATION 9
Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

a.) Specifically, your firm does not perform any identity testing on incoming raw materials.

b.) Your firm does not audit any of your raw material suppliers.

OBSERVATION 10
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no written stability program designed to assess the stability characteristics of drug products. For example, Glutathione 200mg Injection (lot 12191702) was not within its BUD date with a 88.0% potency result on 2/12/18 and Alprostadil/Paparerine/Phentolamine Injection 60mcg, 30 mg, 3 mg (lot 11141713) was not within its BUD date with a 83.2% potency result on 12/26/17.

Product	Lot Number	BUD Date	Sterile/Non-Sterile	Date Produced	Test Date	Test Result	Released to patients
Glutathione 200mg Injection	12191702	90 Days	Sterile	12/19/17	1/10/18 2/12/18	92.5% 88.0%	Yes (b)(4) patient
Alprostadil/Paparerine/	11141713	60	Sterile	11/14/17	11/27/17	95.2%	Yes (b)(4)

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Phentolamine Injection 60mcg, 30 mg, 3 mg		Days			12/26/17	83.2%	patient

OBSERVATION 11

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, your firm does not have any hold time studies for how long glassware used for sterile operations can be stored before use after being depyrogenated in the (b) (4) Furthermore, your firm has not performed any studies to assure a 3-log reduction is achieved for endotoxins.

OBSERVATION 12

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

a.) Specifically, your firm uses (b) (4) for sterile operations of all high-risk sterile products (non-sterile to sterile products). The (b) (4) Temp pressure gauge (Serial Number: (b) (4)) used for performing the (b) (4) (post sterile operations) has never been calibrated. This pressure gauge has been used since your firm began operations in January 2016. Also, your firm does not receive a Certificate of Analysis for (b) (4) used for sterile operations.

b.) Equipment used in sterile operations are not on a calibration program to be calibrated at any frequency. The following pieces of equipment have not been calibrated since your firm began operations

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in January 2016: (b) (4) s, incubators, and (b) (4) Your (b) (4) scale (model #: (b) (4) serial number: (b) (4) used for weighing materials for sterile operations is past due for calibration. On 8/21/18, we observed this scale had a due date sticker of 7/31/18.

c.) The digital temperature recorder of your refrigerator (b) (4) ; model # (b) (4) ; serial #: (b) (4)) used for storing finished drug product has never been calibrated. Your firm has been using this refrigerator in your pharmacy since January 2016.

d.) Your firm has not qualified your (b) (4) (b) (4) and (b) (4) used for producing sterile drugs at your facility.

***DATES OF INSPECTION**

8/20/2018(Mon), 8/21/2018(Tue), 8/22/2018(Wed), 8/23/2018(Thu), 8/24/2018(Fri), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/05/2018(Wed), 9/06/2018(Thu), 9/07/2018(Fri), 9/11/2018(Tue), 9/13/2018(Thu), 10/02/2018(Tue), 10/03/2018(Wed), 10/24/2018(Wed)

X Michael P Sheehan
Investigator
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