DENSON'S SPECIALTY PHARMACY
200 E. WILLOW AVE. SUITE 100
WHEATON, ILLINOIS 60187
PHONE: 630-668-1180
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EMAIL: DENSONSPECIALTY@GMAIL.COM

To: US FDA Chicago District Office
Attn: Chicago District Director-Nicholas Lyons
550 W Jackson Blvd 16th floor
Chicago, Il 60661-5716

12/07/2015

Re: Posting of FDA form 483 Response

Dear Mr Nicholas Lyons,

As the registered agent of Wellcare Rx Investments LLC, please accept this letter as authorization to publish on the US FDA Internet website, Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy response to the FDA Form 483 Notice of Observations, dated 11/18/2015, as submitted to the Chicago-DO, unredacted but without attachments. We understand this response will be posted under the FDA Form 483 Notice of Observations for Wellcare Rx Investments, LLC issued on 11/18/2015 by Investigator Debra Love (CHI-DO).

Sincerely,

Inayat Patel

12/9/2015

Registered Agent

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12/7/2015

To: US FDA Chicago District Office
Attn. Chicago District Director-Nicholas Lyons
550 W Jackson Blvd 16th floor
Chicago, Il 60661-5716

RE: FDA 483 Response

Dear Mr. Nicholas Lyons,

Wellcare Rx Investments LLC entered into verbal negotiations with Mr Ashar Hasan of Med XI LLC in early September 2015, which led to a Letter of Intent on 09/14/2015 to purchase Denson's Pharmacy. The terms of the agreement in the Letter of Intent drafted by our attorney Jay Bogdan specified acquisition of business assets of the pharmacy excluding shares of stock in the business. The asset purchase contract agreement dated 10/07/2015 also states that Wellcare Rx Investments would not be acquiring the liabilities as a result of the transaction. During the negotiations, the members of Wellcare Rx Investments LLC were informed by Mr Ashar Hasan of Med XI LLC regarding the FDA inspection of the pharmacy for sterile compounding. However, FDA investigator Debra Love was not notified of our intent to purchase the pharmacy, nor was there communication between Debra Love and Wellcare Rx Investments LLC before 10/07/2015. As we reached closer to the acquisition date, the members of Wellcare Rx Investments LLC decided not to compound or dispense compounded sterile medications starting from the acquisition date of 10/08/2015. This was expressly communicated from our attorney Jay Bogdan to FDA inspector Debra Love via email on 10/07/2015 and also to Illinois Drug Compliance Investigator Dr Aarti Parikh via email on 10/07/2015. Please refer to the attachments of these emails enclosed.

We understand that the decision to formally issue the FDA form 483 observations by Investigator Debra Love on 11/18/2015 came with some delay and deliberation on the part of CDER. We recognize the complexity in reaching this decision because of the sale of pharmacy assets on 10/08/2015 from Mr Ashar Hasan of MedXI LLC to Wellcare Rx Investments during the last portion of the inspection. However, Wellcare Rx Investments LLC does not agree with the findings of CDER to issue form 483 observations to our corporation. ***All of the observations cited by investigator Debra Love were specifically under the ownership and watch of Mr Ashar Hasan of Med XL LLC.*** As stated above, Wellcare Rx Investments dba Denson's Specialty Pharmacy has not conducted dispensing of sterile compounded medications as of the acquisition date of 10/08/2015. Nonetheless, the members Wellcare Rx Investments LLC are committed to patient safety and will comply and assist the FDA with future request for information.

Investigator Debra Love initiated her inspection of the pharmacy on 8/8/2015 during which time the ownership of the pharmacy belonged to Med XI LLC [This was 2 months prior to Wellcare Rx LLC acquisition of the pharmacy]. The inspection on 10/19/2015 was a pre-483 meeting, and the inspection was concluded on 11/18/2015. The parties present on the last day of the inspection conducted by Debra Love were Mr Ashar Hasan of Med XI LLC, Mr Scott Luckow Rph, and Inayat Patel of Wellcare Rx Investments LLC. Investigator Love issued form 483 and discussed each observation. She made notations on our comments and tried to answer our questions as best as possible. I reiterated to Debra Love that Wellcare Rx Investments had made a conscience decision not to conduct the dispensing of compounded sterile medications as of the acquisition date of 10/08/2015. I supplied Debra Love with our compounded medications dispensing logs from 10/08/2015 through 11/18/2015. I also gave investigator Love a sample copy of letters sent to patients who had received sterile compounded medications prior to 10/08/2015, explaining our inability to supply them with these products. These letters were sent out approximately one week after 10/08/2015. A copy of a letter to a physician at Wheaton eye group was also given to inspector Love explaining of our inability supply a group of patients who received a sterile compounded eye drop. Please refer to the attachments of these documents enclosed.

As stated above, Wellcare Rx Investments LLC will comply and assist the FDA with request for further information if needed. We are committed to providing a high standard of pharmacy services to our patients.

Before Wellcare Rx Investments LLC is able to entertain the idea of initiating the compounding of sterile medications, we would have to conduct a thorough feasibility

study seeking guidance from the FDA, Illinois Board of Pharmacy, consultants in the industry, and current USP standards. Furthermore, we would need to devise our own written policy and procedures, SOP's, education and training including proper aseptic technique. A significant part of this process would also need to identify areas of deficiency, and re-evaluate the policies, procedures and SOP's of Med XI LLC that led to the 483 observations made by Debra Love. Wellcare Rx Investments LLC is dedicated to the safety of our patients. Consequently, we have decided not to compound sterile medications from the acquisition date of 10/08/2015 and do not foresee compounding of these medications in the future. Also, It is for these reasons, we are unable to respond with a corrective action plan for many observations listed on form 483:

The following observations made by Investigator Debra Love are noted and will be corrected insomuch as they may relate to compounding in general:

Observation 12:

Equipment and supplies are not cleaned and sanitized at appropriate intervals to prevent that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

The firm has not qualified and validated the dry heat process in the convection oven Quincy Lab Inc Model 30GC Serial: G3-289, that is used to sterilize the beakers, and stirring bars that are used to produce some sterile drug products. The firm has no evidence that the dry heat process in the convection oven sterilizes the beaker and stirring bars that are used to produce some sterile drug products.

Observation 12 Response:

Although observation 12 was in reference equipment used in sterile compounding, we will take appropriate action to comply with USP 795 for safeguarding cleanliness of equipment immediately.

Observation 14:

Routine calibration, inspection and checking of electronic equipment Is not performed according to a written program design to the assure proper performance.

Specifically, the firm does not have documentation of calibration and maintenance of equipment used in preparation of drug products.

1. *the Mettler-Toledo balance model number PB 603-S, used to weigh out components (chemicals) which are used to prepare drug products does not have a calibration sticker, there is no documentation of periodic calibration by an outside vendor, and there is no documentation of periodic calibration by employees working at the firm.*
2. *There is no documentation of calibration of the thermometers used in the refrigerator (True Manufacturing Company model # GDM - 33 serial number 1 - 3596253) the incubator (brand name Boekel), and the convection oven (Quincy lab inc model number 30 GC serial number G3- 289).*

Observation 14 Response:

The calibration of Mettler-Toledo balance model # PB 603-S and refrigerator thermometers will be completed by 12/31/2015 or sooner.

The following observations made by Investigator Debra Love are noted and will be addressed once we have determined it is plausible to conduct a thorough feasibility study for sterile compounding:

Observation 6:

Separate are defined areas to prevent contamination or mix-ups are deficient regarding operations of drug products.

Specifically,

The design of the clean room to produce sterile human drug products is deficient as follows:

1. *There is no documentation that the clean room where the ISO - 5 laminar flow hood is located has been qualified by initial studies and classified for air quality and for the particle content in the air when it was built. For example the following documentation was not available for review during the inspection:*

a. Documentation of an assessment of the air quality and particle content of their under as-built static conditions.

b. Documentation of assessment of the air quality and particle content of the air under dynamic conditions when production of sterile drugs products occurs.

2 . There is no ISO classification for the surrounding area outside of the ISO - 5 laminar air-flow hood.

3.There is no pressure differential cascade between the clean room and the surrounding area outside of the entry door in order to control contamination from entering the clean room where the sterile drugs are produced.

4.There is no designated area for example and ante-room for gowning. Gowning is performed in the cleanroom restoril drugs are produced.

Observation 6 Response:

We acknowledge that the design of the area used to compound sterile medications by Med XL LLC is in need of modifications in order to comply with USP 797 standards.

Observation 16:

Buildings used in the manufacture, processing, packing or holding of drug product do not have the suitable size to facilitate cleaning, maintenance, and proper operations.

Specifically,

On 08/12/15, I observe the following conditions in the clean room at the firm where sterile drug products are produced.

1.Shelves and carts used in the clean room are made of material that cannot be easily decontaminated.

a. A small laminate covered wood ledge containing a bag of wipes, plastic bins, and a telephone next to the ISO - 5 laminar air-flow hood.

b. A metal shelf containing supplies in plastic bins on the opposite side of the ISO - 5 laminar airflow hood. Some of the supplies included a container of pH paper and a box of sterile needles.

c.Several plastic bins with sterile supplies such as gloves, bottles, and caps.

d. Two wooden cards containing plastic bins with sterile supplies stored underneath the counter-top next to the ISO - 5 laminar are air flow hood. Each of the bins had supplies such as sterile gloves, sterile syringes, sterile saline, or water for production.

e. A counter-top next to the ISO 5 laminar air-flow hood containing a small incubator, a centrifuge, a calculator, and a bottle of the Home Depot all purpose sprayer.

2.Equipment was stored in the clean room that was not used to prepare sterile drug products.

a. *A small incubator was stored on the counter-top next to the ISO - 5 laminar air-flow hood.*
b. *A small centrifuge was stored on the counter-top next to the ISO - 5 laminar air-flow hood.*

Observation 16 Response:

We acknowledge the area where sterile medications were compounded by Med XL LLC need removal of stated items, rearrangement and/or removal of shelving, and the stated area also needs to be modified and organized in order to comply with USP 797 standards.

As stated above, we cannot respond to the other observations because they specifically relate to deficiencies in the P&P's, SOPs, and lack of implementing a training and education plan by Med XL LLC. It is one thing to identify root causes and implement a plan of action one has personally taken, It is quite another thing to resolve and take corrective measures as a result of another corporation's actions.

Thank You,

Inayat Patel

12/9/2015