**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service
Food and Drug Administration
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215

August 13, 2013

Caroline D. Juran, Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Maryland Drive, Suite 300
Henrico, VA 23233-1463

Dear Ms. Juran:

The purpose of this letter is to refer to the Virginia Board of Pharmacy (BOP) for appropriate follow-up the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed at a pharmacy licensed by the Virginia BOP, Rx South LLC, dba Rx3 Pharmacy, located at 12230 Ironbridge Road, Suite C, Chester, Virginia, during an FDA inspection.

Virginia BOP asked FDA to inspect the firm because of the BOP's concern that Rx3 was engaging in manufacturing activities, specifically the production of large volumes of injectable vitamin drug products (Medi-bolic Booster and Pyridoxine100mg/ml /Thiamine 20mg/ml) without patient-specific prescriptions for weight loss clinics in 16 states. The inspection occurred on December 4-7, 12, and 14, 2012. FDA's investigator was accompanied by Virginia BOP inspectors for two days of the inspection. Attached is a redacted copy of an FDA Form-483 that documents our investigator's observations from the inspection, which we previously provided to the Virginia BOP on January 11, 2013.

During the inspection, information from the pharmacy's owner, Mr. Currin, indicated that the majority of the firm's compounding operations involve compounding drug products based on individual patient prescriptions received prior to compounding. During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Rx3 Pharmacy and determined based on this sample that this firm appears to obtain valid prescriptions for individually-identified patients for most of the drug products that it compounds and dispenses. However, according to Mr. Currin, Rx3 routinely compounded Medi-bolic and Pyridoxine/Thiamine Injectables without receiving an individual patient prescription and Rx3 distributed these compounded products to approximately (b)(4) weight loss clinics in 16 states. Since the inspection, however, Rx3 has informed FDA that Rx3 no longer supplies these clinics.

In February, 2013, the firm advised FDA that it was not at that time compounding products without patient-specific prescriptions.[1]

Based on information reviewed during this inspection and based on discussion with the firm shortly after the inspection, and because this firm represented that it receives prescriptions for all of the products it compounds, this firm's drug production activities, at the time of the discussion with the firm, appear more like those within the bounds of traditional pharmacy practice.[2]

However, during the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that could lead to contamination of drugs, potentially putting patients at risk. FDA believes that these deviations should be corrected to help prevent any future quality problems with drug products made by this firm. Examples of deviations observed during our inspection include:

1. The firm's program to ensure that each process used is able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations. The firm's media fill studies only involved a small number of vials. However, the firm's process for the production of injectables can involve producing a significantly higher number of vials in a single batch of product.

   The firm claims that they are addressing this issue, in part, by updating their media fill procedure to more closely simulate the frequently used, complex manipulations performed by personnel. We recommend that the modified media fill practices be audited as part of the state's follow up activities.

2. The aseptic practices employed by personnel at the firm are inadequate and increase the risk of microbial contamination of the product. The investigator observed that personnel:
   - Introduced nonsterile supplies and materials (e.g., nonsterile ingredient containers) into the aseptic processing area without any disinfection.
   - Had bare wrists exposed while performing manual aseptic operations in the critical area.
   - Touched the bottom of closures with their gloved hands during manual stoppering of vials for injectable products.
   - Stored open sterile vials within the critical area for multiple days without protective cover.

   The firm committed to have personnel appropriately re-trained by an outside party. We recommend that adequacy of aseptic practices be a major focus area of the state's follow up audits.

3. The firm does not adequately verify the effectiveness of the sterilization methods to ensure that injectable products prepared from non-sterile ingredients are sterilized.

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[1] See attached response letter dated February 4, 2013 from Christopher K. Currin, R.Ph. to Evelyn Bonnin, Baltimore District Director.

[2] If the firm begins to compound drugs without receiving prescriptions for individually-identified patients, FDA's view of its status may change.

The firm claims that they verified the effectiveness of the sterilization methods used, but failed to document the verification. They committed to re-verify these methods on an ongoing basis and to document the results, and the outcome of these efforts should be evaluated as part of the state's follow up activities.

4. The firm failed to use adequate methods to perform sterility testing on finished sterile drug products. Sterility test methods used by the firm did not include microbial growth media that would detect the presence of anaerobic bacteria.

   The firm committed to perform sterility tests that conform to official methods and to use growth media that would detect the presence of anaerobic bacteria. We recommend that the testing of batches for critical attributes such as sterility continue to receive focus in state audits.

Rx3 committed to FDA in its February 4, 2013, response to the Form FDA-483 to correct the deviations. To help prevent any future quality problems with drug products made by this firm, the promised corrective actions must be comprehensively and sustainably implemented. We understand that you already have taken some actions with regard to this firm. On January 17, 2013, the Virginia BOP entered an Order of Summary Restriction, restricting the license of Rx3 Pharmacy's pharmacist-in-charge to "supervise or allow any sterile compounding to be done." As part of this Order, the Virginia BOP required that Mr. Currin recall certain drugs and provide evidence of compliance with certain USP Chapters, including 797. We are aware that on February 28, 2013, the Virginia BOP stayed that Order, and Mr. Currin was permitted to supervise and perform sterile compounding.

Because the deviations are not complex to correct and are readily correctable, the firm has agreed in writing to correct the violations, and FDA believes that the corrective actions can be overseen by the State, FDA does not intend, at this time, to take further action with regard to the findings of this inspection. Therefore, FDA is referring this matter to the Virginia BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be further violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Ernest F. Bizjak, Compliance Officer, at 410-779-5715, or by email at ernest.bizjak@fda.hhs.gov.

Sincerely,

Evelyn Bonnin
District Director
Baltimore District Office

# Rx³ Compounding Pharmacy

*"Specializing in Custom Compounding"*

February 4, 2013

Evelyn Bonnin
District Director
Baltimore District
Office of Regulatory Affairs
Food & Drug Administration
6000 Metro Drive Suite 101
Baltimore, MD 21215

Re: Rx3 Pharmacy's Response to FDA Form 483
FEI Number 3008723337

Dear Ms. Bonnin:

I am writing to provide a supplement to the response I submitted on January 3, 2013.

On January 29, 2013, Rx3 Pharmacy received news from [redacted (b) (4)] that it had been replaced by a different supplier of compounded products. See Attachment 1 for the [redacted (b) (4)] notification letter. Because supplying compounded services to the various [redacted (b) (4)] resulted in the largest total volume of Rx3 Pharmacy's sterile compounding services, Rx3 Pharmacy will produce a substantially lower volume of compounded products going forward. Moreover, we expect this change to result in the elimination of all or nearly all of our bulk compounding services. Specifically, with respect to future operations, we are not presently aware of any products that would be produced without a patient-specific prescription, and we anticipate that any exceptions to this would be for relatively small amounts of products that are produced exclusively in response to a well-documented request for an individual physician's in-office use only. Accordingly, the business and practices that led to the conclusion that Rx3 Pharmacy was a "manufacturer"—a conclusion with which we continue to disagree—no longer apply.

Although the above change effectively renders the few outstanding issues from our 483 response moot, below is an update nonetheless.

- With respect to Observation 2, please be aware that we began using [redacted (b) (4)] growth medium on January 11, 2013. See Attachment 2 for representative testing logs using [redacted (b) (4)]

- With respect to Observation 3, the 30 day results from the December 12, 2012 BUD analysis of the Medi-bolic Booster product was received on February 1, 2013. As indicated, the potency of all four components of the product sample were well within the 90%-110% range set forth in USP 795 (and incorporated in USP 797 for sterile products). See Attachment 3 for potency reports. Note: this analysis will continue for a total of 90 days.

2230 Ironbridge Road, Suite C • Chester, Virginia 23831 • www.rx3pharmacy.com
Pharmacy (804) 717-5000 • Toll Free (888) 384-5470 • Fax (804) 717-8300

- With respect to Observation 4, [redacted] (b) (4) continues to work on its system to include the modified skip lot testing protocol. The protocol software will be implemented immediately upon receipt.

- With respect to Observation 7, [redacted] (b) (6) has signed up for the May 10 and 11, 2013 "Aseptic Technique Compounding Training," presented by the America College of Apothecaries. See Attachment 4 for registration confirmation.

In light of the above, I believe there is no more basis for the FDA to conclude that Rx3 Pharmacy is engaged in any "manufacturing." Accordingly, I respectfully ask that this matter be closed as soon as possible.

Once again, please do not hesitate to contact me for additional clarification at either (o) 804-717-5000 or (c) [redacted] (b) (6). I can also be reached by electronic mail at chrisc@Rx3pharmacy.com.

Sincerely,

Christopher K. Currin, R.Ph.
Managing Partner and Director of Pharmacy

cc: Nathan A. Kottkamp

Attachments:

1. [redacted] (b) (4) Notification Letter
2. Testing Logs and other information regarding [redacted] (b) (4)
3. [redacted] (b) (4) Potency Reports on Medi-bolic Booster
4. Aseptic Technique Compounding Training Registration

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 6000 Metro Dr. Suite 101<br>Baltimore, MD<br>21215 410 779 5455<br>Industry Information: www.fda.gov/oc/industry | 12/4-7, 12, & 14/2012<br>FEI NUMBER<br>3008723337 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christopher K. Currin, Co-owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Rx South, LLC. dba. Rx3 Pharmacy | 12230 Ironbridge Rd. |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Chester, VA 23831 | Drug Manufacturer |

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 (I) (WE) OBSERVED:

Laboratory Control System

OBSERVATION 1

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, lots of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable manufactured prior to 11/5/2012, were not routinely tested for sterility. Vials of Medi-bolic are labeled with an expiration period of 90 days and vials of Pyridoxine/Thiamine are labeled with an expiration period of 60 days. Both products are held at room temperature.

Between 1/1/2012 and 11/4/2012, (b) (4) lots of Medi-bolic and (b) (4) ots of Pyridoxine/Thiamine were manufactured. Of those, only four lots of Medi-bolic and four lots of Pyridoxine/Thiamine were tested for sterility.

OBSERVATION 2

Established test procedures are not followed.

Specifically, USP Chapter <71>, "Sterility Tests" requires the use of Fluid Thioglycollate Medium (FTM) and Soybean–Casein Digest Medium (TSB), or equivalent commercial media, for sterility testing in order to ensure the growth of anaerobic bacteria, aerobic bacteria, and fungi. However, the current sterility testing performed on all lots of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable via direct inoculation uses only TSB media.

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|---|---|---|---|
| |  | Rachel C. Harrington, Investigator | 12/14/2012 |

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| CITY, STATE AND ZIP CODE<br>Chester, VA 23831 | TYPE OF ESTABLISHMENT INSPECTED<br>Drug Manufacturer |

OBSERVATION 3

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

Specifically, there is no written stability testing program in place to continuously monitor the stability of batches on the market, and assess the on-going state of control of the manufacturing process.

Additionally, of the two lots of Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable tested for initial stability in 2008, one lot did not meet all specifications at the 60-day time point. Pyridoxine/Thiamine lot 02112008@1748 was placed on stability 2/15/2008. The potency/purity result at the 60-day time point for Pyridoxine HCl (Vitamin B-6) was 88.23%, whereas the specification is [redacted] (b) (4) No investigation was conducted into the failing stability results. Vials of Pyridoxine/Thiamine are labeled with a 60-day expiry period.

Furthermore, there is no analytical test data documented to support the 90-day expiry period placed on all vials of Medi-bolic Booster Injectable.

OBSERVATION 4

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, there is no final product potency testing performed on a routine basis for Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable. Sterile and non-sterile finished products are randomly selected to be sent out for potency testing by a contract laboratory. However, since January 1, 2012, there have not been any lots of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable tested for conformance to the identity and strength of each active ingredient.

There have been [redacted] (b) (4) lots of Medi-bolic and [redacted] (b) (4) lots of Pyridoxine/Thiamine manufactured since 1/1/2012.

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| CITY, STATE AND ZIP CODE<br>Chester, VA 23831 | TYPE OF ESTABLISHMENT INSPECTED<br>Drug Manufacturer |

OBSERVATION 5

The environmental monitoring program is inadequate.

Specifically,

a) Personnel glove sampling assessments do not include the monitoring of all fingers on both hands. Employees who work in aseptic manufacturing randomly conduct glove monitoring by pressing their index finger and thumb of one hand onto an agar paddle. During actual operations all fingers are used to manufacture sterile drug products.

b) There is no monitoring of the environment within the ISO Class 5 laminar air flow hood during aseptic manufacturing operations of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable, including air and surface sampling.

c) The gloves of the technician performing aseptic manipulations are not monitored during each lot of Medi-bolic and Pyridoxine/Thiamine manufactured. For example, [redacted] (b) (4) technicians who are allowed to manufacture high-risk sterile products have not conducted glove monitoring in the last six months.

Production and Process Control

OBSERVATION 6

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

Specifically,

a) The [redacted] (b) (4) has not been validated to demonstrate that it can reproducibly remove viable microorganisms from lots of Medi-bolic Booster Injectable and Pyridoxine/

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Thiamine 100mg/mL/20mg/mL Injectable drug product.

In addition, there is no data to support the establishment of the [redacted] (b) (4) limit for the [redacted] (b) (4), which is used to verify the integrity of the [redacted] (b) (4) post product [redacted] (b) (4). Furthermore, the results of the [redacted] (b) (4) are not documented.

b) The media fill test procedure does not closely simulate the most challenging or stressful conditions encountered in typical high-risk sterile production. For example, the current media fill test involves [redacted] (b) (4) However, the typical process for a lot of Medi-bolic Booster Injectable drug product involves [redacted] (b) (4)

OBSERVATION 7

Aseptic manufacturing practices are inadequate.

Specifically, on 12/6/2012, aseptic filling operations were observed for Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable lot# 12042012:27, during which the following objectionable observations were noted:

- Bare wrist skin exposed within the ISO Class 5 Laminar Air Flow Hood (LAFH)
- Non-sterile objects, including Ziploc bags containing stoppers and caps, were placed inside the hood without being first wiped down with isopropyl alcohol (IPA)
- Technician seated immediately against the edge of the LAFH with forearms occasionally resting on the corner of the stainless steel table
- Technician's gloved hand contacted with bottom of stoppers during manual stoppering of vials
- Storage of open vials within the ISO Class 5 LAFH for multiple days
- Bulk container of Pyridoxine/Thiamine hanging in front of critical zone during filling operations*

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* The impact of the bulk container on laminar airflow within the LAFH has not been evaluated via a smoke study.

In addition, on 12/5/2012, a technician was observed to put on sterile gloves while inside the ISO Class 5 LAFH, allowing the non-sterile outer packaging to contact the inside of the hood.

OBSERVATION 8

Batch production and control records are not kept for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically, ~98% of the manufacturing records for lots of Medi-bolic Booster Injectable and Pyridoxine/ Thiamine 100mg/mL/20mg/mL Injectable drug products prepared during the ten month time period between 1/1/2012 and 10/31/2012 are missing.

In addition, 30 manufacturing records reviewed for lots prepared between 2/15/2012 and 12/4/2012 were missing the following items:

- Name of person performing and checking each significant production step
- Dates of each significant production step
- Representative label
- Actual and theoretical yield
- Containers/closure lot numbers
- Complete manufacturing instructions, including steps to be taken after sterile filtering of the bulk, mixing times, and bulk hold times

Furthermore, six of the eleven Medi-bolic manufacturing records and seven of the nineteen Pyridoxine/Thiamine manufacturing records reviewed were missing component lot number(s) and/or the lot number of the sterilizing (b) (4) used.

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OBSERVATION 9

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the manufacturing processes for Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable have not been adequately validated to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. For instance, the specific mixing times required for uniform distribution of components and bulk hold times have not been determined through controlled studies.

OBSERVATION 10

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, an error report entitled, "Daily PQC Compounding Process Related Event Report Form", dated 1/4/12, states that vials of Pyridoxine/Thiamine were labeled with the wrong drug label. However, the report does not document the impacted lot number, corrective actions taken, or preventative actions implemented to prevent reoccurrence.

Facilities and Equipment System

OBSERVATION 11

Equipment qualification is not performed according to a written program designed to assure proper performance.

Specifically, the [redacted] (b) (4), installed in 2007, which is used to sterilize lots of

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vials and stoppers used in the packaging of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable, has not been qualified to assure proper performance. In addition, the [redacted] (b) (4) is not routinely calibrated to assure the temperature probe is accurately reporting data. Furthermore, there is no documentation of the [redacted] (b) (4) verification test, which uses a biological indicator, to assure that the equipment is performing adequately. Finally, the maximum load pattern for th[redacted] (b) (4) has not been validated.

Materials System

OBSERVATION 12

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, components used in the production of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable, are not tested for conformance with appropriate specifications of purity, strength, and quality, particularly the total bioburden of non-sterile materials. The drug product components include the [redacted] (b) (4)

OBSERVATION 13

Containers and closures are not tested for conformance with all appropriate written procedures.

Specifically, vials and stoppers used in the packaging of Medi-bolic Booster Injectable and Pyridoxine/Thiamine 100mg/mL/20mg/mL Injectable are not tested for conformance to appropriate specifications.

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| | RCH | Rachel C. Harrington, Investigator | 12/14/2012 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."