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 Baltimore, MD 21215 410 779 5455 Industry Information: www.fda.gov/oc/industry	12/4-7, 12, & 14/2012
	FEI NUMBER 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, 120 lots of Medi-bolic and (b) lots 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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	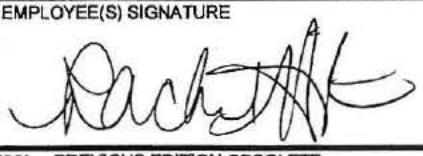	Rachel C. Harrington, Investigator	12/14/2012

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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 (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 (b) lots of Medi-bolic and (b) lots of Pyridoxine/Thiamine manufactured since 1/1/2012.

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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, (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 (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 (b) (4) limit for the (b) (4), which is used to verify the integrity of the (b) (4) post product (b) (4). Furthermore, the results of the (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 (b) (4) . However, the typical process for a lot of Medi-bolic Booster Injectable drug product involves (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) 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 (b) (4) [redacted], 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 (b) (4) r is not routinely calibrated to assure the temperature probe is accurately reporting data. Furthermore, there is no documentation of the (b) (4) verification test, which uses a biological indicator, to assure that the equipment is performing adequately. Finally, the maximum load pattern for the (b) (4) (b) (4) r 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 following: Pyridozine Hydrochloride USP, Thiamine Hydrochloride USP, Choline Chloride USP, Methionine USP, Cyanocobalamin USP (Vitamin B12), Chlorobutanol NF Hydrous, Chromium Chloride Hexanhydrate Reagent, Inositol FCC, Water for Injection USP, and Benzyl Alcohol NF Solution.

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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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."