DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	08/12/2015 - 11/19/2015* FEI NUMBER 3011707930

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Inayat (NMI) Patel, Registered Agent for Wellcare Rx Investments LLC

FIRM NAME	STREET ADDRESS
Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy	200 E Willow Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wheaton, IL 60187-5463	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 I OBSERVED:

OBSERVATION 1

During a field examination of drug products at your facility the following was observed:

Specifically,

On 8/14/15, I observed a vial of sterile human finished drug product Chlorpromazine HCL 25mg/ml, production lot # 05-070815, prepared on 7/8/15 and expires 10/8/15, with what looked like particles floating in the drug product.

OBSERVATION 2

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

Specifically,

During the aseptic preparation of sterile Atropine 0.01% Ophthalmic Drops, firm lot # 01-082715, performed on 8/27/15 by a technician in the ISO-5 laminar air flow hood, I observed the following deficiencies in aseptic technique:

1. There is no documented decontamination of the ISO-5 laminar air flow hood prior to use. For example, I did not observe the technician wipe down the laminar air flow hood with sterile (b)(4) before performing aseptic processing of the sterile drug product.

2. Packages containing sterile items necessary for production were not decontaminated/wiped down with sterile (b)(4) before placing/introducing them into the ISO-5 laminar air flow hood. For example, on 8/27/15, I observed the following: I observed the technician place the

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package containing the (b) (4) 1% Atropine (b) (4), 1%, (b) (4), (b) (4) expires (b) (4), in the laminar air flow hood. (b) (6) did not disinfect the outside of the package before placing it in the laminar air flow hood.

3. Packages containing sterile items necessary for production were opened outside of the laminar air flow hood exposing sterile contents to the non-sterile room air. For example, I observed the following.
   a) I observed the technician open three sterile wipes outside of the laminar air flow hood on (b) (6) right side and then place the wipes on the surface of the laminar air flow hood. (b) (6) used the sterile wipes to wipe the injection port of the (b) (4)

   b) I observed the technician open the wrappers on three sterile syringes outside of the laminar air flow hood and place them in the laminar air flow hood before using them: a sterile (b) (4) syringe with (b) (4); a sterile (b) (4) syringe with (b) (4) containing a sterile (b) (4) needle; and a sterile (b) (4) syringe with (b) (4)

   c) I observed the technician open the wrapper of a sterile (b) (4) needle outside of the hood and place the needle with shield in the laminar air flow hood to use on the sterile (b) (4) syringe with (b) (4).

   d) I observed the technician remove two (b) (4) dropper bottles, (b) (4) Bottle, (b) (4) sterile (b) (4) size, with sterile caps, from the container that they came in. This was done outside of the laminar air flow hood and then the caps bottles were placed in the hood. (b) (6) exposed the sterile bottles to the air in an unclassified room.

   e) I observed the technician remove two caps for the dropper bottles, (b) (4) Bottle, (b) (4) sterile (b) (4) size, from the container that they came in. This was done outside of the laminar air flow hood and then the caps were placed in the hood. (b) (6) exposed the sterile caps to the air in an unclassified room.

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OBSERVATION 3

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

Specifically,

The apparel worn by personnel while conducting aseptic processing of sterile human drug products does not adequately protect the drug products as follows. For example, on 8/27/15, I observed a technician prepare the sterile drug product, Atropine 0.01% Ophthalmic Drops, firm lot # 01-082715, prepared on 8/27/15 and expires on 9/27/15 in the ISO-5 laminar air flow hood in the clean room.

1. The technician had on a non-sterile gown, non-sterile mask, non-sterile bonnet, and non-sterile booties.
2. I observed exposed skin on the face of the technician while the drug product was being prepared.
3. The sterile gloves were opened outside of the ISO-5 laminar air flow hood and then put them on to prepare the sterile drug product.

OBSERVATION 4

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

Specifically,

1. The firm has never performed environmental monitoring during the production of sterile human

drug products. For example, on 8/27/15 I observed the production of Atropine 0.01% Ophthalmic Drops, firm lot # 01-082715, prepared on 8/27/15 and expires on 9/27/15, in the ISO-5 laminar air flow hood and no environmental monitoring was being performed during production.

a) The firm has never performed monitoring for viable microbiological contamination in the cleanroom including inside of the laminar air flow hood under static or dynamic conditions.

b) The firm has never performed non-viable particulates monitoring of the cleanroom including inside of the laminar air flow hood under static or dynamic conditions.

2. The firm has never performed personnel monitoring after the production of sterile human drug products. For example, on 8/27/15 I observed the compounding of Atropine 0.01% Ophthalmic Drops firm lot # 01-082715, prepared on 8/27/15 and expires on 9/27/15, in the ISO-5 laminar air flow hood and no personnel monitoring was performed during production.

3. There is no designated area, for example, an anteroom, for gowning. Gowning is performed (b) (4) [redacted].

OBSERVATION 5

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

Specifically,

1. The firm has not validated the aseptic processing of sterile drug products by performing media fills. For example, the following drug products have been sterilized by (b) (4) [redacted] using (b) (4) [redacted] and no media fills have been performed.

   a) Cyclosporine (A) 1 % Ophthalmic, firm lot # 13-071615, prepared 7/16/15 and expires

10/16/15.

b) Vancomycin 25 mg/ml Ophthalmic, firm lot # 23-081115, prepared 8/11/15expires 14 days.

c) Chlorpromazine HCL 25 mg/ml Injection, firm lot # 05-070815, prepared 7/8/15 and expires 10/8/15.

2. The firm has not conducted smoke studies in the critical areas to demonstrate uni-directional airflow and sweeping action over and away from the product under dynamic conditions.

3. The firm failed to validate the (b) (4) used to sterilize some ophthalmic and intramuscular injectables drug products produced from (b) (4) drug products. In addition, the firm has not established (b) (4) bioburden limits in order to determine if it exceeds the (b) (4) (b) (4). For example, the following sterile drug products are (b) (4) sterilized using (b) (4).

a) Cyclosporine (A) 1 % Ophthalmic, firm lot # 13-071615, prepared 7/16/15 and expires 10/16/15.

b) Vancomycin 25 mg/ml Ophthalmic, firm lot # 23-081115, prepared 8/11/15 and expires 14 days.

c) Chlorpromazine HCL 25 mg/ml Injection, firm lot # 05-070815, prepared 7/8/15 and expires 10/8/15.

OBSERVATION 6

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

Specifically,

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

1. There is no documentation that the clean room where the ISO-5 laminar air 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 the particle content of the air under as-built static conditions.

b) Documentation of an assessment of the air quality and the particle content of the air under dynamic conditions when production of sterile drug 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 cleanroom and the surrounding area outside of the entry door in order to control contamination from entering into the cleanroom where sterile drugs are produced.

4. There is no designated area, for example, an anteroom, for gowning. Gowning is performed (b) (4) .

OBSERVATION 7

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in processing.

Specifically,

The preparation of sterile drug products does not include documentation of the testing of the (b) (4) used during aseptic (b) (4) of drug products which are required to be sterile. For example, the following drug products are (b) (4) using (b) (4) but the firm did not perform (b) (4) of the (b) (4) .

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a) Cyclosporine (A) 1 % Ophthalmic, firm lot # 13-071615, prepared 7/16/15 and expires 10/16/15.

b) Vancomycin 25 mg/ml Ophthalmic, firm lot # 23-081115, prepared 8/11/15 and expires 14 days.

c) Chlorpromazine HCL 25 mg/ml Injection, firm lot # 05-070815, prepared 7/8/15 and expires 10/8/15.

OBSERVATION 8

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Sterile human drug products have never been tested for sterility and pyrogens.

1. **Chlorpromazine HCL 25 mg/ml Injection, Rx # (b) (4), (b) (6) produced 7/8/15, lot 06-070815, expires 10/8/15, was not tested for sterility and pyrogens.**
2. **Atropine 0.01% Ophthalmic Drops, Rx # (b) (4), (b) (6), produced 9/2/15, lot 08-090215, expires 10/2/15, was not tested for sterility and pyrogens.**
3. **Edeate Disodium 10% Injection, Rx # (b) (4), (b) (6), produced 7/6/15, lot 03-070615, expires 8/6/15, was not tested for sterility and pyrogens.**

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OBSERVATION 9

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

Specifically,

The firm does not have documentation of stability testing data to support the expiration dates assigned to the sterile human drug products. For example, the following sterile human drug products have expiration dates that are based on (b) (4) (b) (4) but the firm has never sent out the finished sterile human drug products to assure the finished drug products meets the specifications for identity, strength, and quality, throughout the assigned expiration date.

1. C-Chlorpromazine HCL 25 mg/ml Injection, Rx # (b) (4), (b) (6) produced 7/8/15, lot 06-070815, expires 10/8/15.
2. Atropine 0.01% Ophthalmic Drops, Rx # (b) (4), (b) (6), produced 9/2/15, Lot 08-090215, expires 10/2/15.
3. Edeate Disodium 10% Injection, Rx # (b) (4), (b) (6), produced 7/6/15, lot 03-070615, expires 8/6/15.

OBSERVATION 10

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,

The following human drug products have never been tested for potency before release.

1. Chlorpromazine HCL 25 mg/ml Injection, Rx # (b) (4), (b) (6), produced 7/8/15, lot 06-070815, expires 10/8/15, was not tested for potency.

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2. Atropine 0.01% Ophthalmic Drops, Rx # (b) (4), (b) (6) produced 9/2/15, lot 08-090215, expires 10/2/15, was not tested for potency.

3. Edeate Disodium 10% Injection, Rx # (b) (4), (b) (6), produced 7/6/15, lot 03-070615, expires 8/6/15, was not tested for potency.

OBSERVATION 11

Each lot of a component liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

Certificates of Analysis for components used to produce sterile human injectable drug products do not indicate that they have been tested for pyrogens or bacterial endotoxins. For example, the following components were used to produce sterile human injectable drug products.

1. The Certificate of Analysis for Hydroxyprogesterone (b) (4), (b) (4), does not list pyrogens or bacterial endotoxin test results. This lot was used to produce the following sterile drug products that are injected intramuscularly.

   a) Hydroxyprogesterone (b) (4), (b) (4), was used to make a (b) (4) (b) (4), prepared on (b) (4), expiration (b) (4)
   b) (b) (4) was used to prepare Hydroxyprogesterone Caproate 250 mg/ml in oil, prescription # (b) (6), (b) (4) lot # 11-050615, prepared on 5/6/15, patient expiration 8/1/15.
   c) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml in oil, prescription # (b) (6), (b) (4), lot # 02-050715, prepared on 5/7/15, patient expiration 8/1/15.
   d) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml Injection (intramuscular), prescription # (b) (6), (b) (4), lot # 04-060815, prepared on 6/8/15, patient expiration 8/1/15.
   e) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml Injection (intramuscular), prescription # (b) (6), (b) (4), lot # 16-070915, prepared on 7/9/15, patient expiration 8/1/15.

2. The Certificate of Analysis for Papaverine (b) (4) does not list pyrogens or bacterial endotoxin test results. This lot was used to compound the following sterile drug products.

a) Papaverine (b) (4), was used to prepare Papaverine (b) (4) prepared on (b) (4), expiration (b) (4)

b) (b) (4) was used to prepare (b) (4), prepared on (b) (4), expiration (b) (4)

c) (b) (4), was used to prepare Urology Triple Mix 30-2-20, Rx # (b) (4), (b) (6), lot # 15-082715, prepared on 8/27/15, expiration 10/27/15.

d) (b) (4) was used to prepare Urology Triple Mix 30-1-10, Rx # (b) (4), (b) (6), lot 02-082915, prepared on 08/29/15/15, expiration 10/27/15.

OBSERVATION 12

Equipment and utensils 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 (b) (4), that is used to sterilize the (b) (4) that are used to produce some sterile drug products. The firm has no evidence that the (b) (4) sterilizes the (b) (4) that are used to produce some sterile drug products.

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OBSERVATION 13

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 firm does not have current written procedures related to the compounding of sterile drug products.

A. **There is no written procedure that requires a sporicidal agent to be used in the disinfection of the laminar air flow hood and the clean room where sterile drugs are produced.**
B. **There is no written procedure that states when the HEPA filters inside the ISO-5 laminar air flow hood in the cleanroom should be changed and documented.**

C. **The written procedures in the (b) (4) Manual are not current and have not been reviewed since August 2004. Some of the procedures are not adequate for their intended use and/or are not followed. Some of these written procedures include the following.**
   1. **(b) (4) -Clean room and Hood Maintenance.**
      a) **The procedure does not state to document the cleaning and disinfection of the laminar air flow hood and the cleaning and disinfection of the clean room. There is no documentation of the cleaning and disinfection of the laminar air flow hood and the clean room.**
      b) **In the procedure under the section of Cleaning Schedule (b) (4) it states to (b) (4) . Currently sterile (b) (4) is used to clean the laminar air flow hood (b) (4) There is no documentation of the cleaning and disinfection of the laminar air flow hood and the clean room with sterile (b) (4) .**
      c) **The procedure states to (b) (4) . On 8/12/15, I observed a dirty grey tacky mat on the floor upon entry into the cleanroom. It was later removed and replaced with a new tacky mat the same day by management.**
      d) **In the procedure under the section of Cleaning Schedule (b) (4) it states to (b) (4) . There is no documentation of this cleaning and the procedure does not state that documentation is required for this cleaning.**

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e) In the procedure under the section of Cleaning Schedule (b) (4) it states to (b) (4) but it does not state to document the check and replacement of the (b) (4). There is no documentation of the replacement of the (b) (4) in the over the last 5 years and management does not remember the last time when the (b) (4).

f) The procedure does not state what parameters should be checked on an annual basis for certification of the laminar air flow hood and that the results should be reviewed by management for accuracy.

2. Pharmacy Environment- Clean Air Center ISO Class 5 (formerly called Class 100) (b) (4) Laminar Flow Hood Maintenance.
   a) The procedure does not state to document the cleaning and disinfection of the laminar air flow hood which is used to prepare sterile drug products.
   b) The procedure is not current in that a (b) (4) is no longer used to disinfect the hood. On 8/27/15, I observed sterile (b) (4) being used to clean the hood after the preparation of a sterile drug product.
   c) There is no documentation of the (b) (4) cleaning of the HEPA filter grill/guard in the laminar flow hood.
3. Denson's Compounding Pharmacy I.V. Admixture QA Procedures:
   The following sections of this procedure have never been performed.
   a) Environmental Monitoring: Air Sampling and Surface Testing for the laminar flow hood have never been performed.
   b) Sanitizing Agents: The sterile (b) (4) is not (b) (4) (b) (4) as stated in the procedure.
   c) Personnel and Process Validation Using Media-Fill Testing has never been performed.

D. The written procedures in the Policy and Procedures Manual are not current and have not been reviewed since 2012. Some of the written procedures include the following: Product/Item Recall (b) (4) reviewed July 10, 2012; Adverse (b) (4) Events (b) (4) reviewed August 2, 2012; and Grievances and Complaints reviewed August 4, 2012.

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OBSERVATION 14

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

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

1. **The (b) (4) balance, (b) (4), 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 the calibration of the thermometers used in the refrigerator (b) (4), the incubator (brand name (b) (4), and the (b) (4).**

OBSERVATION 15

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

Specifically,

Components, both active ingredients and non-active ingredients, are not tested before being used to prepare human sterile drug products. For example, the following components are used to prepare human sterile drug products.

1. **Hydroxyprogesterone (b) (4) (b) (4) (b) (4), lot # (b) (4) prepared on (b) (4) was made with the following components.**
   a) Active ingredient Hydroxyprogesterone (b) (4) (b) (4) (b) (4).

2. **(b) (4) (b) (4) (b) (4), prepared on (b) (4), expires (b) (4), was made**

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with the following components.

a) Active ingredient Papaverine (b) (4) [redacted]

(b) (4) [redacted]

OBSERVATION 16

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

Specifically,

On 8/12/15, I observed the following conditions in the cleanroom at the firm where sterile drug products are produced.

1. Shelves and carts used in the cleanroom 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 air flow 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 carts containing plastic bins. The carts were stored underneath the counter top next to the ISO-5 laminar air flow hood. Each of the bins had supplies such 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 (b) (4) [redacted], and a bottle of (b) (4) [redacted].

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 (b) (4) was stored on the counter top next to the ISO-5 laminar air flow hood.

OBSERVATION 17

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

Specifically,

Time limitations have not been established for some (b) (4) used to prepare sterile drug products prepared by the firm. For example, the following (b) (4) was used to prepare sterile drug products and time limitations have not been established to determine how long it can be used.

Hydroxyprogesterone (b) (4) (b) (4), was used to make a (b) (4) (b) (4), prepared on (b) (4), and expires (b) (4). The firm does not have data to support that the (b) (4) can be held for (b) (4) and is stable for this time period. (b) (4) sterile drug products that are injected intramuscularly.

a) Hydroxyprogesterone (b) (4) (b) (4), was used to make (b) (4), prepared on (b) (4), expiration (b) (4).
b) (b) (4) was used to prepare Hydroxyprogesterone Caproate 250 mg/ml in oil, prescription # (b) (4), (b) (6), lot # 11-050615, prepared on 5/6/15, patient expiration 8/1/15.
c) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml in oil, prescription # (b) (4), (b) (6), lot # 02-050715, prepared on 5/7/15, patient expiration 8/1/15.
d) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml Injection (intramuscular), prescription # (b) (4), (b) (6), lot # 04-060815, prepared on 6/8/15, patient expiration 8/1/15.
e) (b) (4) was used (b) (4) to prepare Hydroxyprogesterone Caproate 250 mg/ml Injection (intramuscular), prescription # (b) (4), (b) (6), lot # 16-070915, prepared on 7/9/15, patient expiration 8/1/15.

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FOOD AND DRUG ADMINISTRATION

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550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	08/12/2015 - 11/19/2015* FEI NUMBER 3011707930

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Inayat (NMI) Patel, Registered Agent for Wellcare Rx Investments LLC

FIRM NAME	STREET ADDRESS
Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy	200 E Willow Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wheaton, IL 60187-5463	Producer of sterile drugs

OBSERVATION 18

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

Specifically, the firm has no data to demonstrate the effectiveness of the sporicide, (b) (4) as a sporicidal agent. It is used in the (b) (4)

*** DATES OF INSPECTION:**
08/12/2015(Wed), 08/13/2015(Thu), 08/14/2015(Fri), 08/18/2015(Tue), 08/24/2015(Mon), 08/25/2015(Tue), 08/27/2015(Thu), 09/01/2015(Tue), 09/08/2015(Tue), 09/11/2015(Fri), 10/01/2015(Thu), 10/19/2015(Mon), 11/19/2015(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Debra I. Love, Investigator Debra I. Love	11/19/2015