DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/22/2017-3/24/2017*
	FEI NUMBER 3011752429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William O. Richardson , CEO

FIRM NAME	STREET ADDRESS
Isomeric Pharmacy Solutions, LLC	2401 South Foothill Dr, Suite D
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84109-1479	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A) Environmental Monitoring (EM) Excursions – Investigations are not always conducted or are incomplete for alert and action limit excursions for viable and non-viable environmental monitoring.

a) There have been approximately 85 viable alert and action level personnel and environmental excursions in your classified clean room. There has been no documented product risk assessment and corrective and preventative actions are not identified and documented on your Monitoring Event Form (MEF). Additionally, as part of your investigations, the identification of the microorganism recovered is not included in product risk assessment, or corrective and preventative action. For example:

i) MEF No. 17009 documents positive (1 CFU) personnel monitoring results on the (b) (4) (b) (4) of an operator collected on 1/4/2017. MEF No. 17013 documents two positive (TNTC) (b) (4) surface environmental monitoring samples collected on 1/10/2017, (b) (4) of Triamcinolone Acetonide 40 mg/mL Preservative-Free (PN (b) (4)), Lot 12004. The micro identification was reported for both action level events by your contract laboratory on 1/27/2017 as chaetomium sp. (fungi genus). On 1/20/2017 (seven days before the micro identification results were reported) the MEF meeting used to discuss product risk associated with MEF No. 17009 and MEF No. 17013 was held. Lot #12004 was released on 2/6/2017 and distributed.

b) Your firm failed to document and investigate non-viable particle excursions in your ISO 5, ISO 7

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and ISO 8 classified areas per your SOP-607-02, Environmental & Personnel Monitoring. There is no documentation to support that (b) (4) logs were reviewed and since the previous inspection (6/2016) the following action level particle excursions were observed without any documented investigation:

- 218 action level particle excursions in the (b) (4) (action limit: (b) (4) (b) (4)).
- 206 action level particle excursions in the (b) (4) (action limit: (b) (4) (b) (4)).
- 239 action level particle excursions in the (b) (4) (action limit: (b) (4) (b) (4)).
- 373 action level particle excursions in the (b) (4) (action limit: (b) (4) (b) (4)).
- 221 action level particle excursions in the (b) (4) where sterile product is produced (b) (4) (action limit: (b) (4)
- 600 action level particle excursions in the (b) (4) where sterile product is produced (b) (4) (action limit: (b) (4)

*Approximately (b) (4) batches of sterile finished products have been produced and released using at least one of the areas listed above.

B) Out of Specification (OOS) Results – Investigations are not always conducted when products fail to meet your internal specification for potency, sterility, or bacterial endotoxin. Additionally there has been no assessment of how these failures affect any previous or future production. The following are examples of commercial and stability batches that had OOS results associated with them:

a) Commercial Batches
   i) Testosterone Cypionate/Testosterone Propionate 200/20mg/mL Injectable Solution (b) (4) , Lot 11042 (PN (b) (4)), failed sterility release testing.
   ii) Triamcinolone Acetonide 40 mg/mL Preservative-Free Injection (PN (b) (4), Lot 04035, failed endotoxin release testing.

b) Stability Batches
   i) Triamcinolone Acetonide 40 mg/mL Preservative-Free Intrathecal Injection – Labeled BUD

180 days - Failed endotoxin at t= (b) (4)

(1) Lot 03041 – Compounded Date: 04-22-2016; Test Completion Date: 04-29-2016 – 59.28 EU/mL against a specification of (b) (4)

(2) Lot 02052 – Compounded Date: 03-22-2016; Test Completion Date: 04-05-2016 – 39.22 EU/mL against a specification of (b) (4)

ii) Testosterone Cypionate 200 mg/mL, Testosterone Propionate 10 mg/mL, Vitamin D3 200 IU/mL – Labeled BUD 90 days – Failed Vitamin D3 potency at t= (b) (4) (b) (4)

(1) Lot 08027 – Compounded Date: 09-23-2016 Original Test Completion Date: 01-3-2017 – 172 % against a specification (b) (4)

(2) Re-Tests Completion Date: 01-19-2017 – 116% and 119% against a specification of (b) (4) (b) (4)

iii) Methylprednisolone Acetate/Lidocaine HCl 40/10mg/mL – Labeled BUD 180 days - Failed preservative content (antimicrobial effectiveness) at t= (b) (4) Specification of (b) (4)

(1) Lot 06252015@19 Compounded Date: 06/25/2015; Test Completion Date: 01/08/2016 – 70.6%.

(2) Lot 08052015@14 Compounded Date: 08/05/2015; Test Completion Date: 02/03/2016 – 69.1%.

C) Visual Inspection Rejects – Your firm does not conduct investigations into vials rejected during your (b) (4) visual inspection process. Additionally, you have not established a reject limit for the number of vials that can be rejected for a given batch size. For example, your batch record for Triamcinolone Acetonide 40 mg/mL Preservative-Free Injection, Lot #07021, compounded on 8/12/2016, documents 488 vials were visually rejected out of (b) (4) filled vials. No investigation was conducted and the batch was released 9/13/2016.

D) Production Process Change – When changes in production are made as a corrective action to identified production process issues, investigations are not always extended to determine the impact on already distributed product. For example, in September 2016 your firm changed the (b) (4)

(b) (4) for Testosterone Cypionate/Testosterone Propionate 200/20mg/mL Injectable Solution from (b) (4) as a result of consumer complaints associated with stopper brittling and coring. Your firm performed a (b) (4) titled "(b) (4) " to demonstrate that the (b) (4) did not result in the same container closure integrity issues that were identified with (b) (4) However, your firm failed to extend the scope of this investigation to determine the impact of the closure system issues into the approximately (b) (4) lots of (b) (4) distributed product on the market at that time.

E) Deviations – Your firm failed to perform investigations and determine the impact of deviation events on previous or future production. Additionally, your firm has not been able to provide documentation to support that the corrective actions stated in deviation documents occurred. For example, the following deviations are related to (b) (4) excursions for (b) (4)

a) On three consecutive days from July 13th to July 15th 2016, the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) . Each deviation stated that the corrective action taken was that (b) (4) "was red-tagged and removed from service until a calibration and system check is performed and the unit is cleared to return to service." However, batch records indicate the equipment was still used on the two days which followed the initial deviation event on 07/13/2016. The following three deviations occurred in July 2016 for lots of released product:
   i) DVN-16186 initiated on 07/13/2016 for lot 06002 for Methylprednisolone Acetate/Lidocaine HCl 80/10mg/mL.
   ii) DVN-16182 initiated on 07/14/2016 for lot 05045 for Methylprednisolone Acetate/Lidocaine HCl 40/10mg/mL.
   iii) DVN-16180 initiated on 07/15/2016 for lot 05052 for Methylprednisolone Acetate/Lidocaine HCl 40/10mg/mL.

b) Deviation document DVN-16197 initiated on 09/08/2016, for released lots 07023 and 07032 of Methylprednisolone Acetate/Lidocaine HCl 40/10mg/mL, states that equipment (b) (4) (b) (4) the (b) (4) There was no investigation into this (b) (4) Additionally, DVN-16197 states that (b) (4) "is scheduled to be recalibrated during the week of 15 Sept 2016." However, the Equipment Log for (b) (4) does not indicate that recalibration occurred during the week of 15 Sept 2016 and

servicing records show that the equipment was never serviced between 11/23/2015 and 10/03/2016.

F) Media Fill Failures – Microbial growth observed during media fills lack investigations to include the potential impact to other commercial product produced during the same time period. During the media fills for Prednisolone Acetate Ophthalmic Suspension USP, 1%, (b) (4) media fills were documented as sterility failures. No investigations were conducted to determine the source of the repeated failures and no corrective and preventative actions were implemented which would determine the impact on future production for the following media fills: (b) (4)

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 2

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

Since the previous inspection, your firm has documented 33 customer complaints and none have been investigated. Although you have not fully evaluated these complaints as they may apply to past or future production of these products, your quality control unit continues to approve batches for distribution. Since the previous inspection (6/2016) your firm has released approximately (b) (4) batches of finished sterile drug product. Of these complaints there were:

A) Eleven unique complaints related to infection, pain, swelling or knotting at injection site for Testosterone Cypionate/Testosterone Propionate 200/20mg/mL (PN (b) (4)). These lots were produced via (b) (4)

B) Six unique complaints related clumping in finished product, Methylprednisolone Acetate/Lidocaine

HCl 40/10mg/mL (PN (b) (4)). Four of these six complaints involved lot 05052.

C) Five unique complaints related to black particles, fragments, or coring in Methylprednisolone Acetate/Lidocaine HCl 40/10mg/mL (PN (b) (4)) and Testosterone Cypionate/Testosterone Propionate 200/20mg/mL Injectable Solution (PN (b) (4)). These lots were produced via (b) (4) (b) (4) and (b) (4)

OBSERVATION 3

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically,

A) Product beyond use dates (BUD) are not adequately supported by stability studies. Your firm did not follow stability protocols in regards to the (3) minimum number of batches on stability, testing intervals, and statistical analysis. These BUD stability failures are reflective of the production process used to support current finished product production and distribution. Additionally, the data results collected as part of your real-time stability studies do not support your shelf-life conclusions. For example:

a. Per MS-1920, revision date 11/29/2016, Triamcinolone Acetonide 40 mg/mL Preservative-Free has a BUD of 180 days. Your endotoxin specification for this intrathecal injectable product is no (b) (4) however, the stability lots 02052 and 03041 had out of specification t=0 days endotoxin levels of 39.22 and 59.28 EU/mL, respectively. Additionally, the stability studies were not performed in the same container-closure system in which this product is marketed. During the stability study, (b) (4) vials were used for stability study lots while the product is marketed in a 2 mL vial.

b. Per MS-PN1200, revision date of 05/12/2016, Testosterone Cypionate/Testosterone Propionate 200/20mg/mL has a BUD of 180 days (b) (4) of this product. (b) (4), was included in your stability study. Additionally, for lot (b) (4) there was no sterility testing performed after the last passing sterility result of (b) (4) in support of a 180 day BUD.

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B) Additionally, seven of the ten BUD stability protocols reviewed do not appropriately specify container storage conditions to ensure that drug product comes in contact with the closure system. These protocols state vials should be stored upright or do not state the storage position of vials.

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 4

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

There is not adequate written justification for re-work process deviation from your master batch records (MBR). Deviation No. DVN-16269, documents the planned re-work procedure of lots 09021 and 09029, of Testosterone Cypionate 200 mg/mL/Testosterone Propionate 10 mg/mL/Vitamin D3 200 IU/mL (PN(b) (4) that failed finished product assay for Vitamin D3 (lot 09021=41.62% and 09029=47.32%). In the "Justification" section of Deviation Form, FRM-850-02-02, you did not address potential quality risk's associated with process deviations from your validated procedures listed in your Master Batch Record.

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 5

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

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Specifically,

A) Written procedures and cleaning practices for your ISO 5 hoods in the ISO 7 (b) (4) Room could lead to contamination of the aseptic production area. For example:
   a. Grates were removed from the ISO 5 hoods by operators, set on the floor and leaned against walls of the ISO 7 suite for cleaning. There was no recertification of the ISO 5 hoods after cleaning. Your cleaning SOP, SOP-302-01, does not include details on HEPA recertification after cleaning and approved cleaning agents to use during cleaning.

B) Your firm has not performed process validation or media fills for the aseptic production of Phenylephrine HCl/Tropicamide 2.5%/1% ophthalmic solution since a process change occurred in approximately (b) (4) . For example, the following critical steps were added to MBR-1300-01, Rev D, without validation:
   a. Step (b) (4)
   b. Steps (b) (4)
   c. Steps (b) (4)

C) Your in situ air pattern analysis (smoke studies) were not conducted under dynamic conditions simulating routine production processes (i.e. aseptic operations conducted by processing employees). For example:
   a. Smoke studies did not evaluate operators introducing processing equipment or components into the ISO 5 areas or normal aseptic vial/dropper filling operations conducted by processing employees.
   b. Smoke studies did not evaluate whether operators or activities in the ISO 7 suite affect the unidirectional airflow from the HEPA filters in the ISO 5 hoods where sterile drug products are produced. On 2/23/2017, during production of Triamcinolone Diacetate 40 mg/mL, Lot 13026, operators were observed walking behind operators working in the ISO 5 hood.

D) Currently there are no procedures to ensure the aseptic conditions are appropriate for sterile production after (b) (4) the HEPA air handling system. As part of your (b) (4) cleaning, you

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are (b) (4) HEPA air filtration system without re-certification to conduct (b) (4) per your cleaning SOP-302-01. For the (b) (4) (b) (4) he HEPA filtration system is (b) (4) pressure differentials are not maintained between your ISO 5, ISO 7, and ISO 8 classified areas.

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 6

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

Since approximately 6/2016, your firm has used an un-calibrated and un-qualified in-house built (b) (4) ((b) (4) to evaluate the (b) (4) to render injectable finished drug products free of objectionable microorganisms. There have been approximately (b) (4) lots of (b) (4) product produced and released using this piece of equipment.

OBSERVATION 7

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,

Your firm has failed to validate your (b) (4) process used during the processing of bulk/(b) (4) suspension products (e.g. all Methylprednisolone Acetate and Triamcinolone products). Additionally, your firm has not qualified your (b) (4) units.

A) During production, there is no in-process check for particles size to ensure product is (b) (4)

B) NCR-16160 for lot 09007 (PN(b) (4)), documents on 10/10/2016, "After visual inspection, majority of vial contained clumps of drug product, varying in size and quantity, which could not be (b) (4) " Your (b) (4) process was identified as the root cause. The batch was "reprocessed" on a (b) (4), re-visually inspected, and released by your QA unit on 10/17/2016.

C) On 2/28/2017, during visual inspection of lot 13027 (PN(b) (4) finished product visual inspectors were observed removing vials with apparent "clumps" even after (b) (4) the vial. The visual reject vials observed with "clumps" were set aside for use as finished product samples and were not identified nor documented as visual inspection rejects on the batch record.

D) Since June 2016, there have been six customer complaints (covering lots 04031, 05052, 06002, 06021, and 06034) related to clumping and unable to draw product up in syringe.

OBSERVATION 8

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically,

Your quality control unit fails to review and approve records without completely investigating these records for errors. For example:

A) None of the eight drug product stability protocols which your firm uses to support BUD for commercial product on the market have been reviewed and approved by your quality control unit. For example, the Document Post-Approval for Methylprednisolone Acetate/Lidocaine HCl 80/10mg/mL states "By review and acceptance of this complete protocol, an appropriate stability period for Methylprednisolone Acetate/Lidocaine HCl 80/10mg/mL has been determined." The Document Post-Approval has not been reviewed and approved by your quality control unit but your

firm uses the data obtained from this stability protocol to support the 180 BUD for Methylprednisolone Acetate/Lidocaine HCl 80/10mg/mL.

B) The performance qualification of (b) (4) (VPQ-015), page 1 documents the quality assurance review and approval on 01/20/2017. Pages 5 and 6 of this approved document (VPQ-015) contained required tables which were not completed:
   a. All personnel participating in the execution of the protocol.
   b. Equipment and materials used in the execution of the protocol.

C) Document Change Order, DCO00079, documents the quality assurance review and approval of the master batch record for Triamcinolone Acetonide 40 mg/mL Preservative-Free which was signed off by quality assurance on 03/15/2016. Page 1 of the master batch record states the formulation number is (b) (4) which corresponds to Triamcinolone Acetonide/Lidocaine HCl 40/10mg/mL.

OBSERVATION 9

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

Steps are not taken to prevent contamination of drug product and defined classified areas of your facility. For example:

A) Operators, including those who weigh potent raw ingredients, are permitted to reuse non-sterile gowning increasing the likelihood of drug product cross-contamination. Operators are permitted to reuse foot covers, hair nets, and lab coats at their discretion and use the same gowning day after day.

B) On 02/23/2017, a sterile room operator was observed continuously crossing over the line of demarcation defining the ISO 7 and ISO 8 designated areas of the ISO 7/8 Ante Room while

conducting sporicidal cleaning. The operator did not change gowning during this process and was observed crawling on the floor between ISO 7 and ISO 8 classified areas.

C) During a cleaning on 02/23/2017, we observed an operator rolling a cart over the demarcation line between the ISO 7 and ISO 8 classified areas. This cart, which holds your (b) (4) is not monitored as part of your firm's environmental monitoring program per SOP-607-01.

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 10

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices and written procedures required by current good manufacturing practice regulations.

Specifically,

A) Employees conducting visual inspections of finished sterile injectable drug products for critical defects (including particulates) are not adequately trained and qualified. For example:
   a. On 2/21/2017, a batch of Triamcinolone Acetonide 40 mg/mL Preservative-Free Injection, lot 13023, was (b) (4) visually inspected by your visual inspectors and 18 vials were rejected. On or about 2/22/2017, your pharmacist observed (b) (4) additional vials with un-identified black particles during (b) (4). This batch has not received final disposition by QA.
   b. The two employees were not qualified per your firm's SOP-913-01, Visual Inspection of Finished Sterile Products, REV B. Additionally, employees were observed not following your SOP by conducting inspection of solutions (b) (4) (b) (4) (b) (4)

B) Employees who produce drug products are not properly trained on written procedures relating to their job functions. Employees who conduct operations in the ISO 5 and ISO 7 classified suites were observed not gowning in accordance to clean room garb SOP-303-01 Rev B, with a revision date of

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12/19/2016. We observed the following examples of employees violating clean room gowning procedures while donning sterile garb for clean room access:

a. On 02/27/2017, an operator wearing sterile coveralls, was observed leaning against the western ISO 7/8 Ante Room door as she attempted to don sterile boot covers prior to conducting operations in the ISO 7 suite.
b. On 02/22/2017, a sterile room operator was observed first donning sterile boot covers and then eye-wear prior to entering the ISO 7 suite to (b) (4) Cyanocobalamin/Methionine/Inositol/Choline Cl 1/25/50/50 mg/mL, lot 13025. Per section 8.4.10 through 8.4.11, operators must (b) (4) .
c. On 2/22/2017, an operator was observed donning a new pair of sterile gloves directly over an older pair of gloves. Section 8.4.11.3 states "Aseptically don a new pair of sterile gloves. Remove current pair of sterile gloves from hand. Apply (b) (4) to hands and allow to (b) (4) "

This is a repeat observation from the previous FDA inspection conducted June 20th-29th, 2016.

OBSERVATION 11

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your firm is not currently conducting any finished product testing for particulate matter in your sterile drug products. You have no scientific justification to support not testing all finished sterile drug products for particulate matter. Furthermore, your Material Specification sheet for Testosterone Cypionate 200 mg/mL, Testosterone Propionate 10 mg/mL, and Vitamin D3 200 IU/mL (PN (b) (4), effective 2/17/2017, requires testing per USP <788> Particulate Matter in Injections.

OBSERVATION 12

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Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed.

Specifically,

The suitability of the sterility method, USP <71>, Sterility Tests, used by your contract laboratory to conducted sterility testing on all your finished products was not completed prior to conducting sterility testing. The method suitability for Triamcinolone Diacetate 40 mg/mL (sterile intramuscular injection), PN(b) (4), and Triamcinolone Acetonide 40 mg/mL Preservative-Free Injection (sterile intrathecal/epidural injection), PN (b) (4), were both completed 2/21/2017. From 6/2016 to 2/21/2017, you have produced and released (b) (4) lots ((b) (4) vials) of Triamcinolone Diacetate 40 mg/mL and (b) (4) ots ((b) (4) vials) of Triamcinolone Acetonide 40 mg/mL Preservative-Free Injection.

OBSERVATION 13

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

Specifically,

Since installation in 1/2015 to the beginning of this inspection 2/22/2017, your firm has never re-calibrated your (b) (4) as part of your ISO 5, 7 and 8 (b) (4) . During this inspection, your (b) (4) (b) (4) were re-calibrated and the (b) (4) in (b) (4) ISO 5 hoods ((b) (4) were found to be out of tolerance.

OBSERVATION 14

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

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Your firm lacks adequate written procedures for the use of the (b) (4) agent in your (b) (4) to ensure cleaning of sterile suites prevents contamination. For example:

A) Your (b) (4) agent is (b) (4) per the manufacturer's direction for use.

B) The (b) (4) is stored uncovered in the un-classified laboratory area and not cleaned prior to use in the ISO classified suites.

***DATES OF INSPECTION**

2/22/2017(Wed),2/23/2017(Thu),2/24/2017(Fri),2/27/2017(Mon),2/28/2017(Tue),3/01/2017(Wed),3/02/2017(Thu),3/03/2017(Fri),3/13/2017(Mon),3/14/2017(Tue),3/15/2017(Wed),3/16/2017(Thu),3/17/2017(Fri),3/23/2017(Thu),3/24/2017(Fri)

3/24/2017

X Nayan J Patel

Nayan J Patel
Investigator
Signed by: Nayan J. Patel -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zachary L Stamm, Investigator Nayan J Patel, Investigator 3/24/2017 X Zachary L Stamm Zachary L Stamm Investigator Signed by: Zachary L. Stamm -S	3/24/2017