DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd, 3rd Floor Parsippany NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	11/27-29/2017, 12/1/2017, 12/4-8/2017, 12/12-13/2017
	FEI NUMBER 2242985

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Walter Kelso, Center Manager

FIRM NAME	STREET ADDRESS
PharMEDium Services, LLC	36 Stults Rd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dayton, NJ 08810	Outsourcing Facility

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Drug products failing to meet established specifications are not rejected. Specifically:

a. On 03/11/17, during potency testing of 10 mEq Potassium Chloride in 0.9% Sodium Chloride 1000mL in Bags, lot 170650080D, a failing result was obtained (result 0.009 mEq/mL, specification (b) (4)). Although the batch was given a rejection disposition, a shipment of this batch was distributed on 4/12/17.

b. On 02/15/17, during potency testing of Potassium Phosphate in 0.9% Sodium Chloride 10mMol in 250mL Bags, lot 17044084D, a failing result was obtained (result 0.05555 mMol/mL, specification (b) (4) (b) (4) As part of the laboratory investigation, retesting was performed, and another failing result was obtained (result 0.05623 mMol/mL). The batch was released on 3/3/17, and shipped on 3/6/17.

OBSERVATION 2
There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch, regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.

The below deficiencies are in regard to aseptically filled sterile drug products that may be filled in syringes, bags, or cassettes:

a. There have been approximately 8 confirmed failures for in-house sterility testing of finished sterile drug products since June, 2016 (a (b) (4) is used; lots are sometimes (b) (4) for testing, implicating approx. (b) (4) lots). All of the associated batches that had been (b) (4) for testing were rejected; however, the investigations do not routinely identify the contaminating microorganism, determine which of the (b) (4) batches contributed to the failure (where applicable), or

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adequately assess other batches of drug product that were produced by the same personnel, in the same ISO-5 (b) (4) Laminar Flow Hoods, or used the same production equipment as the failed batches. For example:

i. Investigation DNC-17-503 was raised 4/7/17, following failing sterility results for 7 (b) (4) batches of sterile injectable/infusion Magnesium Sulfate products, and all 7 batches were rejected. Although the production personnel responsible for these batches were assessed through observation for hand-washing technique, sterile gowning and gloving, cleaning and sanitization of the hood, sanitization of gloves and components, and various aspects of aseptic technique, no additional samples (other than those routinely collected) of other products, gowning/gloving, or increased environmental monitoring are collected to determine further potential impact.

ii. Investigation DNC-17-1538 was raised 9/28/17, following failing sterility results for 4 (b) (4) batches of sterile injectable/infusion Potassium Chloride products, and all 4 batches were rejected. The same type of observational assessment described above, for various aspects of gowning/gloving, cleaning and sanitization, and aseptic technique, was performed for the associated production Technicians, but no heightened sampling of other products, gowning/gloving, or increased environmental monitoring was performed following the failure.

iii. Investigation DNC-17-516 was raised 4/11/17, following failing sterility results for 2 (b) (4) batches of sterile injectable/infusion Diltiazem Hydrochloride products, and both batches were rejected. The same type of observational assessment described above, for various aspects of gowning/gloving, cleaning and sanitization, and aseptic technique, was performed for the associated production Technicians, but no heightened sampling of other products, gowning/gloving, or increased environmental monitoring was performed following the failure.

iv. Laboratory Investigation INV-DA-17-33 was raised 4/20/17, following "questionable results" for sterility testing of a single lot of sterile infusion product Potassium Phosphate in 0.9% Sodium Chloride. The lot was rejected, but the investigation does not discuss why the result was interpreted as questionable or whether additional analytical training was necessary (reported that two Analysts disagreed on the result). Subsequent production investigation DNC-17-729 includes an observational assessment of the production Technician that made the batch, but does not include any heightened sampling of other products, gowning/gloving, or increased environmental monitoring following the failure, to assess potential further impact.

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b. Since June, 2016, there have been approximately 6 instances of failing results for in-house endotoxin testing for which the failures were attributed to the (b) (4) ((b) (4) method using (b) (4) (b) (4) preparation and reading). Suitability of the (b) (4) was found acceptable, but in each case, a new sample was collected from the same finished product unit and retested in a (b) (4), with passing results. For example:

i. Failing results were obtained for testing of Oxytocin 30 Units added to 0.9% Sodium Chloride in Bags, lot 170550008D, on 2/28/17 (result: <2.36 EU/mL, limit (b) (4) The standard curve and recovery from the (b) (4) were found acceptable, but the product was retested on a (b) (4), with passing results. The lot was released on 3/8/17.

ii. Failing results were obtained for testing of 0.1% Ropivacaine Hydrochloride in 0.9% Sodium Chloride in Cassettes, lot 173100020D, on 11/7/17 (result: 0.115 EU/mL, limit (b) (4) The standard curve and recovery from the (b) (4) were found acceptable, but the product was retested on a (b) (4), with passing results. The lot was released on 11/10/17.

iii. Failing results were obtained for testing of 0.2% Ropivacaine Hydrochloride in 0.9% Sodium Chloride in Cassettes, lot 173200004D, on 11/18/17 (result: <0.14 EU/mL, limit (b) (4) The standard curve from the (b) (4) was found acceptable, but the product was tested on a (b) (4), with passing results. The lot was released on 11/22/17.

Additionally, no documented training could be provided for this testing method, and other investigations have been raised for issues such as "incorrect (b) (4)," "data not saved," "incorrect (b) (4) used," and "analyst did not load (b) (4)."

OBSERVATION 3

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

Since June, 2016, there have been approximately 4 results of "TNTC [too numerous to count] colony forming

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units" for personnel glove monitoring samples of production Technicians collected during aseptic filling of sterile drug products in (b) (4) Laminar Flow Hoods (b) (4) LFHs). Spore-forming microorganisms have been identified in each case. Other than routine environmental monitoring, there was no additional sampling of other surfaces (e. g., (b) (4)) or equipment to determine the potential source or route of glove contamination, whether cleaning and sanitization remain effective, and whether any further contamination persists. Additionally, there is no targeted assessment of other sterile drug products filled by the same Technicians or in the same (b) (4) LFHs at the time of the failures. For example:

i. "TNTC" was reported for left glove sample of Technician (b) (6) (collected 5/10/17), but there was no additional sampling and testing of sterile products filled by that Technician around the time of the failure, or of the same (b) (4) LFH or other equipment used, to determine if any contamination persisted. The sample plate was sent for organism identification on 5/25/17, finding "Bacillus Oceanisediminis," a "spore forming" organism, for which "the common source…identified is soil." During retesting and (b) (4) sets of investigational glove tests of the Technician on 5/15/17, a failing result of 2 CFU was found, but the "Corrective Action" section of the investigation states "The retest samples were acceptable. The retest samples contained zero colony forming units post incubation." The investigation was completed 7/14/17, approx. 2 months after the failure.

ii. "TNTC" was reported for right glove sample of Technician (b) (6) (collected 8/11/17), but there was no additional sampling and testing of sterile products filled by that Technician around the time of the failure, or of the same (b) (4) LFH or other equipment used, to determine if any contamination persisted. The sample plate was sent for organism identification on 8/24/17, finding "Bacillus Licheniformis," a "spore forming" organism, for which "the common source…identified was soil."

iii. "TNTC" was reported for left glove sample of Technician (b) (6) (collected 5/10/17), but there was no additional sampling and testing of sterile products filled by that Technician around the time of the failure, or of the same (b) (4) LFH or other equipment used, to determine if any contamination persisted. The investigation was completed 8/18/17, approx. 3 months after the failure was found on 5/16/17 and sent for organism identification on 5/19/17 (finding "Paenibacillus glucanolyticus," a "spore forming" organism).

iv. "TNTC" was reported for left glove sample of Technician (b) (6) (collected 8/23/17), but there was no additional sampling and testing of sterile products filled by that Technician around the time of the failure, or of the same

(b)(4)LFH or other equipment used, to determine if any contamination persisted. The sample plate was not sent for organism identification until 9/25/17, finding "Paenibacillus glucanolyticus," a "spore forming" organism.

A sporicidal disinfectant is used on a (b) (4) basis throughout the Clean Room and ISO-5 (b) (4) Laminar Flow Hoods and other surfaces. Although a disinfectant effectiveness study appears to have demonstrated a (b)(4) (b) (4) contact time was sufficient for the sporicide, the supplier recommends a (b) (4) contact time. This contact time and sporidical disinfection frequency have not been revisited since the findings described above, and trending of environmental and personnel monitoring does not target the isolation of spore-forming organisms such as those described in the above examples.

The use of inadequate contact time for a sporicidal disinfectant is a repeat observation from the 4/18/16 to 5/26/16 inspection.

OBSERVATION 4
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not fully in writing.

SOP CPS-313, Aseptic Technique and Classified Area Management, identifies items such as bags of sterile diluent as low risk, due to their receipt from the supplier in a protective overwrap. These items are not required to be re-sanitized when they are transferred from the ISO-7 Clean Room to the ISO-5 (b) (4) Laminar-Flow Hoods (b)(4)LFHs) for filling operations. Such items are (b) (4) in the unclassified preparation room and placed in (b) (4), which are (b) (4) for staging in the ISO-7 Clean Room. Components may then be handled by personnel in the Clean Room for (b) (4), in between which the Technician must handle and scan the paper batch record, which is not printed on sterile or low-particle-shedding paper.

On 12/6/17, we observed this practice during the preparation for filling of Sodium Phosphate added to 0.9% Sodium Chloride 250mL in Bags, lot 173390082D, in which several diluent bags were handled for scanning, then brought into the ISO-5 (b)(4)LFH. The bags were not (b) (4) again (b) (4), and only the injection ports of the bags were sanitized once inside the (b)(4)LFH. Additionally, on that same day, for the

preparation for filling of Neostigmine Methylsulfate 1mg/mL in 5mL Syringes, lot 173390075D, we observed vials of drug product being (b) (4) in ISO-7 at approx. 11:30 AM, after which the Technician handled the paper batch record, then the vials again. The vials were not transferred into the ISO-5 (b) (4) LFH until approximately 11:43 AM.

Since June, 2016, there have been approximately 14 failing test units with microbial growth found during media fill simulations for demonstration of personnel aseptic technique or process validation. Of these 14 units, 8 have been found to be contaminated with various spore-forming Bacillus species, and identification on the remaining 6 contaminated units is pending (found 11/18/17). The media fill failures have been attributed to (b) (4) (b) (4). Associated investigations have not identified any need for process improvement, specifically of SOP CPS-313.

The use of paper batch records in the Clean Room is a repeat observation from the 4/18/16 to 5/26/16 inspection.

OBSERVATION 5
Samples taken of drug products for determination of conformance to written specifications are not representative.

Regardless of batch size, (b) (4) is pulled for sterility and endotoxin testing of all batches, unless the finished dosage unit contains less than (b) (4), in which (b) (4) units are pulled. Since June, 2016, batches between approx. (b) (4) (b) (4) units in size have been produced. According to CPS-790, Using the (b) (4) for Sterility Testing of Compounded Sterile Preparations, a volume between (b) (4) is the minimum sample volume. For example:

a. Phenylephrine Hydrochloride 100mcg/mL in 0.9% Sodium Chloride in 10mL Syringes, lot 173260079D, was produced on 11/24/17 and filled on (b) (4) syringe filling line (b) (4) This batch was compounded and filled into approx. (b) (4), which were then filled into approx. (b) (4) syringes. A (b) (4) was collected for microbiological testing, from which a sample of approx. (b) (4) was tested for sterility.

b. Succinylcholine Chloride 20mg/mL in 5mL Syringes, lot 173250001D, was produced on 11/21/17 and filled on (b) (4) syringe filling line (b) (4) This batch was (b) (4), which

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were then filled into approx. (b) (4) syringes. A (b) (4) was collected for microbiological testing, from which approx. (b) (4) was tested for sterility.

c. Ephedrine Sulfate 5mg/mL in 0.9% Sodium Chloride in 5mL Syringes, lot 173240093D, was produced on 11/21/17 and filled on (b) (4) filling line(b) (4) This batch was compounded and filled into approx. (b) (4), which were then filled into approx (b) (4) syringes. A (b) (4) was collected for microbiological testing, from which approx (b) (4) was tested for sterility.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality, and purity.

Performance of 100% visual inspection of finished sterile drug products for particulate matter is not performed against a dark and light background for visualization of various types of particles throughout the filled container. CPS-788, Visual Inspection, has been established, describing specifically how to perform inspection for each finished unit for IV bags, cartridges, and syringes, but a planned deviation from the procedure has been written, as the light-box with dark and light background described in the procedure is not available for use.

Additionally, although management explained that all (b) (4) filled batches are visually inspected in the ISO-5 (b) (4) Laminar Flow Hood, this is not always documented in the batch record. For example, of (b) (4) recent batch records reviewed (10/19/17 to 11/27/17), 8 did not have a record of visual inspection of finished units:

- Potassium Chloride in 0.9% Sodium Chloride 10mEq in 150mL Bags, lot 173280072D, produced on 11/27/17
- 0.1% Ropivacaine Hydrochloride in 0.9% Sodium Chloride in 100mL Cassettes, lot 172910017D, produced on 10/19/17
- Oxytocin 30 Units added to 500mL 0.9% Sodium Chloride Injection USP Bags, lot 172910034D, produced on 10/19/17
- 0.0625% Bupivacaine Hydrochloride in 0.9% Sodium Chloride in 250mL Cassettes, lot 172910018D, produced on 10/19/17

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• Potassium Chloride in 0.9% Sodium Chloride 40mEq in 500mL Bags, lot 172910005D, produced on 10/19/17
• Diltiazem Hydrochloride 100mg added to 0.9% Sodium Chloride in 150mL Bags, lot 172910032D, produced on 10/19/17
• Vancomycin Hydrochloride 750mg added to 0.9% Sodium Chloride in Bags, lot 172910022D, produced on 10/19/17
• 10mcg/mL Fentanyl Citrate in 0.9% Sodium Chloride in Bags, lot 172910083D, produced on 10/19/17

Although CPS-788, Section 7.6.2.1 requires it, there is no mechanism for visual inspection for particulate matter in syringes filled on (b) (4) syringe filling lines (b) (4) Units go (b) (4) (b) (4) after which they are only externally inspected for defects such as leaking or other damage. For example, no visual inspection is documented for the below batches filled on (b) (4) lines:

• Phenylephrine Hydrochloride 100mcg/mL in 0.9% Sodium Chloride in 10mL Syringes, lot 173210029D, produced on 11/18/17 (b) (4) filled units were labeled)
• Succinylcholine Chloride 20mg/mL in 5mL Syringes, lot 173190087D, produced on 11/16/17 (b) (4) filled units were labeled)

The failure to perform visual inspection of finished sterile drug products against a dark and light background is a repeat observation from the 4/18/16 to 5/26/16 inspection.

OBSERVATION 7
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, environmental monitoring for non-viable particulates (air) is not performed at sufficient frequencies to represent routine production conditions within the ISO-7 Clean Room, each of the ISO-5 (b) (4) Laminar Flow Hoods (b)(4) LFHs), or the (b) (4) syringe filling lines.

This type of monitoring is performed (b) (4) using a (b) (4), during routine operations, with (b) (4) sample collections ((b) (4) from: (b)(4) locations throughout the Clean Room, on the (b) (4) (b) (4) (b)(4) LFH ((b)(4) hood samples total), and (b)(4) locations at each of the (b) (4) filling lines (b)(4 filling line samples total).

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(b) (4) for (b) (4) monitoring have been installed in each of the (b)(4) (b)(4) LFHs in late 2016, and are present on the (b) (4) lines, but it is unclear if these have been qualified, as they are not presently being used.

The insufficient frequency of non-viable air (particulate) monitoring in the ISO-5 (b)(4) LFHs and ISO-7 Clean Room is a repeat observation from the 4/18/16 to 5/26/16 inspection.

OBSERVATION 8
Input to and output from the computer, related systems of formulas, or records or data are not checked for accuracy.

a. There is currently no procedure to describe the review of analytical data used for release testing of finished drug products. There is no documented review of electronic raw data or audit trails, to determine, for example, whether product has undergone unauthorized retesting or whether data has been otherwise manipulated. Testing for potency, sterility, and endotoxin is performed on all finished product batches, and all of the testing equipment captures data electronically (e.g. (b) (4) (b) (4) (b) (4), (b) (4) (b) (4), (b) (4) (b) (4) System for endotoxin analysis, and (b) (4) System). SOP CPS-728, Review of Batch Processing Documentation, does not describe any review of analytical data.

b. Quality Control laboratory worksheets are issued from an electronic document control system, but are accessible to the analyst for unlimited printing, with no date/time-stamp or other issuance controls for reconciliation against other laboratory data.

c. Electronic logs of Quality System reports or files are maintained on uncontrolled spreadsheets on a shared network drive, and there are no controlled paper logs. The electronic spreadsheets do not have an audit trail function to show if previously entered items have been altered or deleted. Logs for the following items are stored in this manner: Notice of Event (NOE) reports, Non-Conformance Reports (NCRs), Laboratory Out-Of-Limit or Out-Of-Specification (OOL/OOS) reports, Customer Complaint reports, and Corrective and Preventive Action (CAPA) reports.

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OBSERVATION 9

The calibration of instruments is not done at suitable intervals in accordance with an established written program.

SOP CPS-747, (b) (4) Check Procedure, does not require daily verification of upper and lower limits that bracket analytical material being measured. (b) (4) verification typically includes a single point. For example:

a. Balance (b) (4) is routinely verified with a single standard weight of (b) (4) before use. On 7/10/17, it was used to measure 16.0mg of a USP reference standard; and on 8/28/17, it was used to measure 8.0mg of a USP reference standard.

b. Balance (b) (4) is routinely verified with a single standard weight of (b) (4) before use. On 10/12/17, it was used to measure 2.01mg of a USP reference standard.

OBSERVATION 10

Packaging and labeling records do not include a specimen of all labels used.

Specifically, examples of the labels applied directly to each finished dosage unit and secondary packaging are maintained in the batch production record, but a record of in-process labels that may be applied to (b) (4) or (b) (4) (b) (4) is not maintained. For example:

a. The batch record for 10 mEq Potassium Chloride in 0.9% Sodium Chloride 1000mL in Bags, lot 170650080D, produced 3/7/17, contains a representative label applied to the finished product bags and the shipper cartons, but not the in-process labels that are applied to the (b) (4) used in (b) (4), or the (b) (4) used in (b) (4)

b. The batch record for Potassium Phosphate in 0.9% Sodium Chloride 10mMol in 250mL Bags, lot 17044084D, produced 2/14/17, contains a representative label applied to the finished product bags and shipper cartons, but not the in-process labels that are applied to the (b) (4) used in (b) (4), or the (b) (4)

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used in (b) (4)

c. The batch record for 0.1% Ropivacaine Hydrochloride in 0.9% Sodium Chloride in 100mL Cassettes, lot 172910017D, produced 10/19/17, contains a representative label applied to the finished cassettes and shipper cartons, but not the in-process labels that are applied to the (b) (4) used in (b) (4) or the (b) (4) used in (b) (4)

d. The batch record for Phenylephrine Hydrochloride 100mcg/mL in 0.9% Sodium Chloride in 10mL Syringes, lot 173260079D, produced 11/24/17, contains a representative label applied to the finished syringes and shipper cartons, but not the in-process labels that are applied to the (b) (4) or the (b) (4)

OBSERVATION 11

The labels of your outsourcing facility's drug products do not include information required by Section 503(B)(a)(10)(A). Specifically:

A. The date the drug was compounded. Examples of drug product labels that do not contain this information:

- 4% Sodium Citrate (Preservative Free) 40mg per mL, 120mg per 3mL (in 5mL Syringes)
- Potassium Chloride in 0.9% Sodium Chloride, 40mEq in 250mL (in Bags)
- Diltiazem HCl 125mg in 125mL 0.9% Sodium Chloride Injection USP (in Bags)
- Oxytocin 30 Units added to 500mL 0.9% Sodium Chloride Injection USP (in Bags)
- Phenylephrine HCl 100mcg per mL, 1mg per 10mL, in 0.9% Sodium Chloride (in 10mL Syringes)
- 0.2% Ropivacaine HCl in Sodium Chloride 0.9% (in Yellow Cassette Reservoirs)

B. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient [this information can be included on the container if there is insufficient space on the product label]. Examples of drug product labels that do not contain this information:

- 4% Sodium Citrate (Preservative Free) 40mg per mL, 120mg per 3mL (in 5mL Syringes)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Nicholas Violand, Investigator Adetutu Gidado, Investsigator	12/13/2017

NV 12/13/17

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd, 3rd Floor Parsippany NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	11/27-29/2017, 12/1/2017, 12/4-8/2017, 12/12-13/2017
	FEI NUMBER 2242985

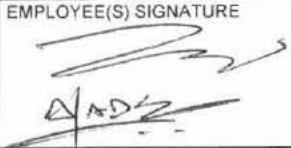
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Walter Kelso, Center Manager

FIRM NAME	STREET ADDRESS
PharMEDium Services, LLC	36 Stults Rd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dayton, NJ 08810	Outsourcing Facility

- Potassium Chloride in 0.9% Sodium Chloride, 40mEq in 250mL (in Bags)
- Diltiazem HCl 125mg in 125mL 0.9% Sodium Chloride Injection USP (in Bags)
- Oxytocin 30 Units added to 500mL 0.9% Sodium Chloride Injection USP (in Bags)
- Phenylephrine HCl 100mcg per mL, 1mg per 10mL, in 0.9% Sodium Chloride (in 10mL Syringes)
- 0.2% Ropivacaine HCl in Sodium Chloride 0.9% (in Yellow Cassette Reservoirs)

The failure to include the date of compounding and a list of inactive ingredients on drug product labeling is a repeat observation from the 4/18/16 to 5/26/16 inspection.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Nicholas Violand, Investigator Adetutu Gidado. Investsigator	12/13/2017

12/13/17