DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/15/2019-5/31/2019* FEI NUMBER 3012034698

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark L. Sangree, President

FIRM NAME	STREET ADDRESS
Pacifico National, Inc. dba AmEx Pharmacy	1515 Elizabeth St Ste J
CITY, STATE, ZIP CODE, COUNTRY Melbourne, FL 32901-3000	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

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

Specifically,

A. On 04/18/2019, I observed your firm's Director of Quality Operations, instructed your pharmacist to discard positive personnel monitoring of (b) (4) ((b) (4) plates into the dumpster after observing possible CFU growth. I followed your pharmacist outside your firm and observed your pharmacist discard the (b) (4) plates into the dumpster. Your pharmacist documented "0" CFUs on the batch record for Bevacizumab 2.5mg/0.1mL (b) (4) Syringe, Lot #190415X, BUD 07/29/2019. However, your Director of Quality Operations and your Sterile Pharmacist admitted they saw a "white dot". According to your written procedures, EP 1-6 for Chest and Cuff Samples, "all CFU growth will be sent to a third- p a r t y laboratory for identification of the microbe to the genus level."

B. Your firm's aseptic operators routinely use (b) (4) pads to rest their elbows, forearms, and wrists during (b) (4) aseptic operations for intravitreal injections repackaged and produced at your firm. The non-sterile gel pads are located inside the LAFH (ISO 5 Classified Area). On multiple days, I observed your aseptic operators touch the non-sterile gel wrist pads with their cuffs, forearms, and elbows during aseptic operations.

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	June P Page, Investigator Brandon C Heitmeier, Investigator Philip F Istafanos, Microbiologist Susan T Hadman, Microbiologist	X June P Page Investigator Signed By 2000405709 Date Signed 06-20-2019 08:05:23	6/20/2019

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According to your firm's Director of Quality Operations, your firm has not conducted any environmental monitoring of these non-sterile gel wrist pads.

C. Your firm does not incubate your purchased (b) (4) plates or your purchased (b) (4) used for (b) (4) routine environmental monitoring (EM) or personnel monitoring (PM) as recommended by the manufacturer to demonstrate growth promotion of yeast, fungus, and/or mold. For example, your firm incubates your purchased (b) (4) plates and (b) (4) at (b) (4) for (b) (4) plates are read. However, these incubation temperatures may not promote growth of yeast, fungus, and/or mold. The Certificate of Analysis (COA) for the purchased (b) (4) and (b) (4) used by your firm references the growth conditions for the recovery of *Candida albicans* is 24°C – 26°C and *Aspergillus brasiliensis* is 20°C – 25°C. In addition, your firm does not use a medium that is optimum for the recovery of yeast, fungus, and/or mold (e.g. Sabouraud Dextrose Agar (SDA)) during EM and/or PM.

D. Your firm has not determined and/or established a program for monitoring the normal flora of your facility.

OBSERVATION 2

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

Specifically,

THIS IS A REPEAT OBSERVATION

A. I observed visible discoloration that appears to be rust on a staging/supply cart located in your firm's cleanroom (b) (4), approximately 3' from the LAFH (ISO 5 classified), EQ ID: (b) (4)

AMENDMENT 1

where aseptic operations occur for sterile intravitreal injections. In addition, your firm's Director of Quality Operations could not provide documentation supporting the suitability of these carts in a classified area.

B. Visible discoloration that appears to be residue buildup was observed on your firm's LAFH (ISO 5 classified), EQ ID: (b) (4) HEPA screen and the interior side of the plexiglass window, where aseptic operations occur for sterile intravitreal injections.

C. Cracks were observed by your firm in the LAFHs (ISO 5 classified) EQ IDs: (b) (4) (b) (4) These cracks were repaired by an employee at your firm. However, according to your firm's aseptic technician, (b) (6), who conducted these repairs stated the epoxy used is not smooth and difficult to clean.

D. Your firm failed to change your LAFH (ISO 5 classified) pre-filters in accordance with the manufacturer's recommendations. The LAFH (ISO 5 classified) are used in the aseptic operations of sterile intravitreal injections produced and repackaged by your firm. The manufacturer recommends the pre-filters are changed (b) (4) to maintain its optimum performance. However, your Director of Quality Operations provided documentation showing the last prefilter changes were performed on 01/03/2018, prior to this date the filters were changed on 06/06/2017.

E. I observed visible signs of what appears to be residue on the ceiling located in your firm's cleanroom (b) (4) (ISO 7 classified area) where aseptic operations take place for sterile intravitreal injections.

F. I observed visible signs of what appears to be debris/dust build up on the ceiling located in your firm's cleanroom (b) (4) (ISO 7 classified area) where aseptic operations take place for sterile intravitreal injections.

OBSERVATION 3

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

Specifically,

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THIS IS A REPEAT OBSERVATION

A. The following deficiencies were observed, for example, but are not limited to:
   1. On 04/15/2019, during the re-packaging operations of Avastin (Bevacizumab 2.5mg/0.1mL (b) (4) syringe), Lot #190415-W, performed by aseptic technician ((b) (6)) in the LAFH (ISO 5 Classified Area), EQ ID (b) (4) was observed moving from a lesser air quality (ISO 7 Classified Area) to cleaner air quality (ISO 5 Classified Area) eleven (11) times without sanitizing their gloved hands.
   2. On 04/15/2019, during the re-packaging operations of Avastin (Bevacizumab 2.5mg/0.1mL (b) (4) syringe), Lot #190415-X, performed by aseptic technician ((b) (6)) in the LAFH (ISO 5 Classified Area), EQ ID: (b) (4) was observed not sanitizing their gloved hands during the movement of materials from a lesser air quality (ISO 7 Classified Area) to cleaner air quality (ISO 5 Classified Area). In addition, aseptic technician (b) (6) was observed blocking first pass air.
   3. On 04/24/2019, 04/29/2019, 05/02/2019, during the re-packaging of Avastin (Bevacizumab) Lot #s: 190424AS; 190429W; and 190502AU, respectively, performed by technician (b) (6) in the LAFH (ISO 5 Classified Area), EQ ID (b) (4) was observed blocking first pass air.
   4. On 05/02/2019, during the re-packaging of Avastin (Bevacizumab) Lot 190502AT, performed by technician ((b) (6)) in the LAFH (ISO 5 Classified Area), EQ ID: (b) (4) was observed blocking first pass air.

B. Your firm failed to conduct viable air sampling during aseptic operations for each lot of Avastin (Bevacizumab) repackaged and (b) (4) (Bevacizumab/Dexamethasone) produced for sterile intravitreal injections.

C. The airflow studies performed in February 2019 were deficient in determining if the air movement from the HEPA filters within the ISO 5 Classified Area, where sterile drug products are manipulated, was unidirectional. In addition, the smoke studies do not simulate all critical steps of your firm's aseptic processing techniques.

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For example, but are not limited to:

1. Your Cleanroom (b)(4) airflow study video shows one (1) aseptic technician performing sterile operations. However, during my visual observation of your aseptic technicians performing (b) (4) sterile operations, (b) (4) aseptic technicians were present in Cleanroom (b) (4) In addition, your room certification report documents Cleanroom (b)(4) is operational for (b) (4) aseptic technicians.
2. Your firm uses forceps to uncap the vial of Avastin (Bevacizumab), your smoke studies do not capture this critical step.
3. Your firm produces (b) (4) (Bevacizumab/Dexamethasone) for intravitreal injections. However, your firm has not conducted any smoke studies for the evaluation for the aseptic processing of this drug product.

D. The aseptic process simulation, such as, media fills performed to qualify technicians in aseptic operations of (b) (4) (Bevacizumab/Dexamethasone) and Avastin (Bevacizumab) were not adequate and do not simulate the most stressful/challenging conditions.

1. For example, but are not limited to, your firm failed to conduct Media Fills in all hoods where aseptic operation is performed. Your firm routinely utilizes (b) (4) LAFHs, located in Cleanroom (b) (4) (b) (4) However, during our review of your firm's production activity corresponding to each date and time media fills were performed, we found your firm failed to conduct Media Fills that simulate the most stressful/challenging conditions:

Date of Media Fill	Hood 7 (EQ ID: (b) (4)	Hood 8 (EQ ID: (b) (4)	Hood 9 (EQ ID: (b) (4)
10/5/2016	No Activity	MF	No Activity
7/27/2017	Lot #170727D	MF	No Activity
9/5/2017	No Activity	Lot #170905E	MF
8/15/2018	No Activity	MF	Lot #180815V
8/21/2018	No Activity	MF	Lot #180821M

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10/05/2018	No Activity	MF	Lot #181005R Lot #181005L

2. According to your firm's Room Certification Reports, cleanroom (b) (4) is qualified for (b) (4) people during operations. Your firm's MF batch records document (b) (4) personnel are present in cleanroom (b) (4) during aseptic operations. However, your firm's PK activity report and batch record review for corresponding date and times of media fill production does not support (b) (4) personnel were present during the time of media fill production.

OBSERVATION 4

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

Specifically,

A. According to your firm's Director of Quality Operations, your firm has not performed process validations for the sterile production of (b) (4) (Bevacizumab/Dexamethasone), intravitreal injections. Your firm has produced this product since approximately 2017, including but are not limited to the following lots:

Lot	BUD
180510P	06/09/2018
180725L	08/24/2018
180925Y	10/25/2018
190227V	03/29/2019

B. Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions. For example, but not limited to, your firm has not established a cleaning validation to ensure your cleaning process removes chemical and microbial residues on the equipment used in your aseptic operations.

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1. In addition, your firm uses hazardous drug products in your non-sterile suite. However, no evaluation was performed to ensure there is no ingress of carcinogenic and/or hazardous material into your firm's aseptic suite (e.g. your firm does not have an air handling unit schematic to assess the airflow throughout your facility). Your firm compounds hazardous drug products, but are not limited to: 5-Fluorouracil, cyclosporine, estradiol, phenytoin, progesterone, sirolimus, spironolactone, tacrolimus, dutasteride, finasteride, fluconazole, misoprostol, testosterone, tretinoin. However, your firm's cleaning procedure does not adequately document it is capable of removing all traces of highly potent or hazardous drugs from non-dedicated equipment to prevent cross contamination.

~~OBSERVATION 5~~

An observation concerning (the QCU lacking responibility to approve/reject drug products (b) (4) - review of documents revealed observation was entered in error after issuance of FDA 483) was removed based on discussion with management.

OBSERVATION 6

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

THIS IS A REPEAT OBSERVATION

Your firm failed to follow your written procedures, QS 2.2: Quality Complaint Handling, as it states the QA Manger will determine whether a complaint requires a non-conformance investigation. In addition, complaints categorized with the following require an investigation:

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- Critical Complaint: A complaint that indicates that the strength, quality, purity, identity, safety or efficacy of the drug product may be compromised and has the potential to cause a life threatening or serious health situation.
- Serious Complaint: A complaint that indicates that the strength, quality, purity, identity, safety or efficacy of the drug product may be compromised, however, does not pose a potential to cause a life threatening or serious health situation.
- Standard Complaint (Trend for 3 or more, investigation required if trend is identified or warranted): A complaint that does not indicate the strength, quality, purity, identity, safety or efficacy of the drug product has been compromised.

However, your Quality Unit failed to conduct a thorough investigation for the following complaints, including, but are not limited to:

A. Since 2016, your firm has received approximately 287 consumer complaints relating to patients experiencing the following, but are not limited to: floaters, plunger not advancing, fibers found on the needles, eye inflammation, loss of visual acuity, etc. According to the last FDA inspection, your firm has been aware of the complaint issues regarding the plunger not advancing since the 2009 Examination of Blocked Avastin Syringes Study which attributed the root cause as low levels of silicone polymers mixing with the Avastin causing needle blockage. Your firm still has not taken the appropriate corrective and preventative actions to address the issue. Since 2016, your firm has received a total of 111 consumer complaints for the plunger not advancing. According to your firm's Director of Quality Operations, these complaints have never been reviewed or investigated by your firm.

    1. In addition, on 05/17/2019, your firm's National Sales Manager, JM, received a complaint for ten (10) syringes of Avastin (Bevacizumab) 1.25mg/0.05mL Monoject Syringe, Lot #190325-N, Exp. 07/08/2019, for the plunger not advancing. However, the National Sales Manager stated they did not complete a complaint form. This negligence resulted in a critical failure for the Pharmacy Quality Unit to conduct an investigation. This incident resulted in the physician "had to repair at least one patient's eye three times

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because of this." Your firm has dispensed (b) (4) syringes of Avastin (Bevacizumab) 1.25mg/0.05mL Monoject Syringe, Lot #190325-N into the market.

B. In 2018, your firm received eighteen (18) serious complaints relating to patients experiencing the following, but are not limited to: endophthalmitis (eye inflammation), eye infections, high eye pressures, color variation, etc. For example, but not limited to, your firm did not conduct an appropriate investigation to establish a root cause, corrective actions, or patient impact related to patients experiencing endophthalmitis (eye inflammation). In addition, your firm failed to report this adverse drug event (ADE) to FDA.

C. Since 2016, your firm documented twenty-eight (28) Adverse Drug Events that were not reported to the FDA related to patients experiencing floaters after receiving intravitreal injections of repackaged sterile Avastin (bevacizumab). In addition, on 06/14/2018, you firm received a letter from BD Medication Delivery Solutions, stating BD has become aware that some BD hypodermic products are being used for intraocular injections which have been associated with "floaters" and endophthalmitis.

OBSERVATION 7

Results of stability testing are not used in determining expiration dates.

Specifically, your outsourcing facility lacked valid analytical and sterility data to support the following:

THIS IS A REPEAT OBSERVATION

A. According to your Director of Quality Operations, your firm has not conducted any stability testing to support the 30-day beyond use date (BUD) assigned to (b) (4) (Bevacizumab/Dexamethasone), used for sterile intravitreal injections.
B. According to your Stability Study Protocol, (b) (4) , conducted by your third party laboratory

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contractor, Avastin (Bevacizumab) repackaged in (b) (4) syringes failed stability testing at (b) (4) the last passing stability testing result documented is t=0-days. However, your firm applies a 105-day BUD to Avastin (Bevacizumab) (b) (4) syringes.

OBSERVATION 8

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

A. Your firm uses, including but are not limited to: spikes, syringes, vials, forceps, and decappers, during aseptic operations of your firm's sterile intravitreal injectable drug products: Avastin (Bevacizumab) and (b) (4) (Bevacizumab/Dexamethasone). However, your firm failed to conduct any additional testing prior to the use of these components in your firm's aseptic operations ensuring the validity of the manufacturer's test results. In addition, your firm does not have a quality agreement with the suppliers and your firm have not qualified these vendors.
B. In addition, your firm does not conduct final release testing for identity, strength, quality and purity for any of the following sterile drug products produced/repackaged at your firm:
    1. (b) (4) (Bevacizumab/Dexamethasone)
    2. Avastin (Bevacizumab)

OBSERVATION 9

Employees engaged in the manufacture, processing and packing of a drug product lack the education, training and experience required to perform their assigned functions.

Specifically,

A. Syringes used during visual inspection trainings are not representative of the actual syringes used

in processing.

For example, but are not limited to:

Your firm uses Monoject syringes (not (b) (4) syringes) during the visual training of your Pharmacist when conducting final visual inspections (i.e. visible particulates, inaccurate dosage, presence of bubbles, discoloration, other).

1. On 04/24/2019, during the visual inspection of Avastin (Bevacizumab) (b) (4) syringe, lot 190415-U, I observed bubbles present during the visual inspection that was passed by your Pharmacist. Your pharmacist explained the size of the bubbles are subjective to the visual inspector and they did not feel the presence of the bubbles I observed should result in a failure.
2. The challenge syringe for particulate matter is not representative of actual conditions.

B. Your pharmacist ((b) (6)), who has been at this firm for approximately 2 months, admitted they observed a "white dot" during (b) (4) routine personnel monitoring, discarded the positive (b) (4) sample into the receptacle bin. This same pharmacist conducts routine (b) (4) plate readings for environmental monitoring and personnel monitoring stated they are not a microbiologist and their training consist of:

(b) (4) (approximately 1 hour);
(b) (4) (approximately 1 hour); and
Their degree as a pharmacist

C. Your aseptic technicians were routinely observed blocking first pass air during aseptic operations.

D. Your aseptic technician was observed to inappropriately don sterile garb prior to engaging in aseptic operations. For example, your technician, (b) (6), was observed placing their sterile hood on, then their sterile suit, then later changed their sterile hood.

1. In addition, all the aseptic technicians engaged in sterile operations were observed with their sterile booties tucked inside their sterile suit.

E. When leaving the anteroom (ISO 8 Classification) and entering the cleanroom (ISO 7

AMENDMENT 1

Classification), your aseptic technicians are trained to remove their sterile gloves, exposing their bare hands in the ISO 7 classified areas; sanitize their exposed bare hands, and don new sterile gloves in the Cleanroom (ISO 7 Classification).

OBSERVATION 10

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established.

Specifically, your Quality Unit failed to conduct any container closure integrity testing for your sterile drug products, Avastin (Bevacizumab) and (b) (4) (bevacizumab/dexamethasone).

In addition, your firm received a letter from BD Medication Delivery Solutions on or around 06/14/2018, which states, BD has become aware that some BD Hypodermic products are being used for intraocular injections. Intraocular use of these products has been associated with events such as 'floaters' and endophthalmitis (inflammation of the interior of the eye)." However, your firm continued to use BD syringes as a primary container closure with a beyond use date (BUD) of 105 days, until approximately 02/2019.

OBSERVATION 11

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

Specifically, according to your Pharmacist-in-Charge, during the aseptic repackaging operation of Avastin (Bevacizumab) using Monoject syringes, for sterile intravitreal injections, your aseptic operators remove the sterile cap of the 4-ml vial, exposing Avastin (Bevacizumab) in an open vial during the aseptic repackaging operation for approximately (b) (4) . (b) (4) , open vial of Avastin (Bevacizumab) approximately (b) (4) (b) (4) of Avastin (Bevacizumab) in each Monoject syringe. Your firm has not established a hold time study to support there is not an increase in bioburden or endotoxin levels.

OBSERVATION 12

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

Specifically, your aseptic technicians are not required to wear a protective face mask under their sterile hood during aseptic operations. The sterile hood specifications provided by your Director of Quality Operations does not document the facemask sewn in your firm's sterile hood prevents microbes from being introduced into your ISO 5 environment.

OBSERVATION 13

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically, on 04/16/2019, I observed your pharmacy technician, (b) (6), whom is not considered a Quality Unit employee, enter your firm's software program to print batch labels for bevacizumab. The user name and password to access this computer is displayed on your firm's monitor, allowing unrestricted and uncontrolled access. The computer is displayed in a high traffic area (e.g. (b) (4) (b) (4) During this inspection, I observed outside contractors pass by this computer on multiple occasions.

OBSERVATION 14

The retention period for drug product reserve samples (except those described in 211.170(b)(2) and (3)) is deficient in that they are not retained for one year after the expiration date of the drug product.

Specifically, your firm does not have any retain samples from previously manufactured lots.

*DATES OF INSPECTION

4/15/2019(Mon), 4/16/2019(Tue), 4/17/2019(Wed), 4/18/2019(Thu), 4/19/2019(Fri), 4/22/2019(Mon), 4/23/2019(Tue), 4/24/2019(Wed), 4/25/2019(Thu), 4/29/2019(Mon), 4/30/2019(Tue), 5/01/2019(Wed), 5/02/2019(Thu), 5/03/2019(Fri), 5/06/2019(Mon), 5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/16/2019(Thu), 5/17/2019(Fri), 5/20/2019(Mon), 5/21/2019(Tue), 5/22/2019(Wed), 5/23/2019(Thu), 5/24/2019(Fri), 5/27/2019(Mon), 5/28/2019(Tue), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri)

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