DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	1/12-15/2016 & 1/21/16
	FEI NUMBER 3012034698

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mark L. Sangree, President

FIRM NAME	STREET ADDRESS
Pacifico National Inc. dba Amex Pharmacy	1515 Elizabeth Street, Suite J
CITY, STATE AND ZIP CODE Melbourne, FL 32901	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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

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

A. The media fills performed to qualify technicians in aseptic re-packaging operations of Avastin syringes were not adequate in that only (b) (4) was required to qualify a technician in aseptic operations as per SOP TR 1.5 Media Fill. However, according to the Pharmacist-in-Charge/Quality Assurance and the Process Organizational Chart-Sterile Compounding, (b) (4) technicians are qualified to perform aseptic re-packaging of Avastin with a maximum of (b) (4) which was not demonstrated during their media fills and therefore, the media fills were not representative of the current process. Upon review of media fill documentation the following deficiencies were found:

a) None of the "qualified" aseptic technicians had adequate documentation of (b) (4) that represents worst-case conditions, i.e. (b) (4) / cleanroom, breaks, gowning/re-gowning, fatigue, etc. that would provide a challenge to aseptic operations. The QA Manager also stated that media fills are not observed by a qualified person to assess aseptic technique and behavior.

b) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) showed (b) (6) only re-packaged (b) (4) but (b) (6) is currently allowed to re-package (b) (4). (b) (4) were sampled for microbiological contamination, no environmental monitoring (gown, air, and surface) was conducted, and the time duration of the media fill was not documented. The media fill check boxes "Pass" or "Fail" were not checked, but the media fill was approved by QA on (b) (4)

c) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) did not record the number of units filled, incubated, or found positive. There was no environmental monitoring (gown, air, and surface) and the time duration of the media fill was not documented. However, this media fill was approved by

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	Jessica L. Pressley	Jessica L. Pressley, Drug Investigator CAPT Ileana Barreto-Pettit, Drug Investigator	01/21/2016

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QA on (b) (4) .

d) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) as "Initial Testing" did not document the number of units filled, incubated, or found positive. There was no environmental monitoring for gown and surface. The media fill check boxes "Pass" or "Fail" were not checked, but the media fill was approved by QA on (b) (4)

e) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) as "ongoing testing" did not record the number of units filled, incubated, or found positive. It only records (b) (4) The fingertip sampling section was crossed out and environmental sampling for gown, air, and surface was not conducted. However, this media fill was checked as "Pass" and was approved by QA on (b) (4) .

f) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) only documented (b) (4) but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4)

g) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) only documented (b) (4) , but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4) .

h) The documentation for the media fill performed by aseptic technician (b) (6) on (b) (4) only documented (b) (4) (b) (4) , but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4)

i) The documentation for the media fill performed by aseptic technician (b) (6) on (b) (4) only documented (b) (4) (b) (4) , but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4)

j) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) as "ongoing testing" did not record the number of units filled, incubated, or found positive, but (b) (6) is qualified to fill up to (b) (4) Environmental sampling for gown and air was not conducted. However, this media fill was checked as

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"Pass" and was approved by QA on (b) (4).

k) The documentation for the media fill performed by aseptic technician (b) (6) on (b) (4) only documented (b) (4) but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4).

l) The documentation for the media fill performed by aseptic technician (b) (6). on (b) (4) only documented (b) (4) but (b) (6) is qualified to fill up to (b) (4) There was no environmental sampling (gown, air and surface), but the media fill was checked as "Pass" and it was approved by QA on (b) (4)

m) The documentation for the ongoing media fills performed by aseptic technicians (b) (6) and (b) (6). on (b) (4) did not record the person that observed the media fills, the quantity of units filled and incubated for each technician, the type of media, lot number, and expiration date used for fingertip sampling, and the signature of the technician performing the media fill. Contemporary documentation of media fills was not performed. A second review of original documentation on (b) (4) showed that fingertip sampling had not been read after (b) (4) (b) (4) of incubation (due after (b) (4)

n) No growth promotion test is performed on the purchased media (b) (4) used in media fills to demonstrate that it promotes growth of gram-negative and gram positive bacteria, yeast and mold.

o) Each (b) (4) of media fill was not (b) (4) as per Job Aid TR 1.5 dated 1/5/15. Instead, the (b) (4).

p) Your firm lacked a disqualification and re-qualification program for aseptic technicians when sterility failures of batches or out-of-specification environmental sampling results are reported. For example, Avastin lot # (b) (4) re-packaged by aseptic technician (b) (6) on 9/15/15 failed sterility testing. The previous media fill performed by this technician on (b) (4) was inadequate as it did not document number of units filled, incubated, and found positive. However, no action was taken by the Quality Unit to restrict this technician from performing aseptic operations until a successful media fill is performed.

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B. During re-packaging operations of (b) (4) Avastin (b) (4), lot # (b) (4) into (b) (4) insulin syringes performed by aseptic technician (b) (6)) in the ISO 5 LAFW on 1/15/16, we observed the following deficiencies in aseptic technique:

a) The (b) (4) used to (b) (4) has a porous rubber handle that cannot be properly sterilized (b) (4) Currently, this tool is only sprayed and wiped with sterile (b) (4) (b) (4)) prior to use in the ISO 5 hood.

b) The technician removed the rubber stopper from the Avastin vial with (b) (6) gloved hands instead of using a sterile tool such as forceps. (b) (6) also re-capped and uncapped the vial once with his gloved hands after 30 minutes of re-packaging in order to wipe and sanitize the work area surface with sterile (b) (4) prior to resuming re-packaging operations.

c) (b) (6) movements in the ISO 5 area were not slow. It was observed that the technician quickly flicked off the disposable plunger cap of each syringe to the side, uncapped the needle, and picked up the opened (b) (4) about 80 times during the (b) (4) re-packaging operation in order to (b) (4) . After (b) (4) directly above the opened vial, the technician (b) (4) before re-capping the needle. SOP TR 1.2 "General Sterile Compounding Procedure" does not provide adequate instructions for acceptable aseptic practices when repackaging sterile drug products.

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

A. The suitability, efficacy, and limitations of disinfecting agents and procedures have not been assessed and approved to ensure potential contaminants are adequately removed from surfaces in the ISO 5 & 7 classified areas. For example,

a) According to Policy CS 1: Control of Systems and Procedures for Maintaining Facilities approved by QA on 9/23/15 and Job Aid CS 1.4: Cleaning and Disinfecting Procedures, the firm uses (b) (4)

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(b) (4), Sterile (b) (4) (b) (4) and (b) (4) however, it was found the following cleaning agents were discontinued or replaced with a different agent within the last few months (no specific date) as follows:

1) (b) (4))- no longer used as it was not sterile.
2) (b) (4) no longer used as it was not sterile.
3) (b) (4) - replaced by (b) (4) to be used (b) (4)
4) (b) (4) - replaced by(b) (4) to be used (b) (4)

There was no documentation for the assessment and approval of any of these cleaning agents and written procedures for their preparation, required contact time, and rotational schedule were not established. In addition, cleanroom cleaning records reviewed from September 2015 through present did not document the (b) (4) cleaning agent used and the reason for (b) (4)

B. Upon observation of cleaning activities and environmental monitoring prior to re-packaging Avastin (b) (4) lot #(b) (4) performed by aseptic technician (b) (6)) on 1/15/16, we noted the following deficiencies:

a) The technician wiped and disinfected the surfaces of only half of the (b) (4) ISO 5 Laminar Airflow Workbench (LAFW) prior to performing aseptic operations. The(b) (4) LAFW is not (b) (4) and (b) (4)) thus increasing the potential for dust particulates from the unwiped side to be introduced into the aseptic work area. This practice of cleaning and sanitizing half of the LAFW surfaces is not in accordance with your SOP CS 1.4 "Cleaning and Disinfecting Procedures."

b) The technician placed the settle plate for viable particulate monitoring on the (b) (4) away from the aseptic work area and blocked by an approximately 6" high plastic bin. This location for air monitoring was not representative of the aseptic work area. SOP EP 1.3 "Air Sampling- Settle plate sampling" states (b) (4) (b) (4) but does not provide additional guidance or precautions to ensure air sampling is representative of the aseptic work area.

3. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. Specifically,

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a) The latest two (2) qualifications of the (b) (4) ISO 7 cleanroom # (b) (4) and the (b) (4) ISO 5 hoods completed on (b) (4) by a contractor do not document if qualifications were performed under static or dynamic conditions with maximum number of personnel. In addition, smoke studies were performed and recorded with (b) (4) (b) (4) which does not represent current practice of up to (b) (4) in cleanroom (b) (4)

b) The firm lacked calibration records for the magnehelic gauges that measure differential pressure in the cleanrooms. There are no written procedures for the calibration of these gauges.

4. Your firm failed to establish and follow an Out of Specification (OOS) Procedure. As a result, your quality unit failed to conduct investigations when the following non-sterile results were received from your contract testing laboratories (CTLs).

a) On 1/26/15, your firm received a non-sterile (evidence of growth) result from your CTL for Lot # 150122C (batch size of (b) (4) Your quality unit failed to request a laboratory investigation from the CTL and failed to conduct a root cause investigation. Instead, your quality unit shipped additional samples to a secondary CTL and those results were reported on 2/12/15 as sterile. Without invalidating the previous non-sterile results with a sound and scientific rationale, your quality unit released and shipped on 2/17/15 and 2/18/15 (b) (4) patient-specific repackaged Avastin syringes from Lot # 150122C to multiple doctors' offices.

b) On 1/23/15, your firm received a non-sterile (evidence of growth) result from your CTL for Lot # 150120I (batch size of (b) (4)). Your quality unit failed to request a laboratory investigation from the CTL and failed to conduct a root cause investigation. Instead, your quality unit shipped additional samples to a secondary CTL and those results were reported on 2/2/15 as sterile. Without invalidating the previous non-sterile results with a sound and scientific rationale, your quality unit released and shipped on 2/17/15 and 2/18/15 (b) (4) patient-specific repackaged Avastin syringes from Lot # 150120I to multiple doctors' offices.

c) On 12/29/14, prior to receiving the sterility test results, your quality unit released and shipped Lot # 141224C (batch size (b) (4) patient-specific repackaged Avastin syringes to a doctor's office. On 1/19/15, your quality unit received an email from your CTL stating a non-sterile result. The CTL investigation stated that it was not a laboratory error. Your quality unit failed to conduct a root cause investigation and instead conducted a recall on 1/20/15 and received a total of repackaged Avastin syringes back (no documentation of the return). A total of 8

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patient-specific repackaged Avastin syringes were administered to patients. Your quality unit failed to follow up with the patients and instead submitted the [redacted] additional samples to the CTL for re-testing. On 2/16/15, your firm received a sterile result from the CTL.

d) On 9/17/15, prior to receiving the sterility test results, and without the quality unit's approval your firm shipped Lot # 150915B (batch size of (b)(4) patient-specific repackaged Avastin syringes to a doctor's office. On 9/30/15, your quality unit received an email from your CTL stating a non-sterile result. The CTL investigation stated that it was not a laboratory error. Your quality unit failed to conduct a root cause investigation and instead conducted a recall on 10/7/15. A total of (b)(4) patient-specific repackaged Avastin syringes were administered to patients. Your quality unit failed to follow up with the patients.

e) On 3/19/15 and 3/23/15, prior to receiving the sterility test results, your quality unit released and shipped Lot # 150316H (batch size of (b)(4) patient-specific repackaged Avastin syringes to multiple doctors' offices. On 4/7/15, your quality unit received an email from your CTL stating a non-sterile result. The CTL investigation stated that it was not a laboratory error. Your quality unit failed to conduct a root cause investigation and instead conducted a recall on 4/7/15 and received a total of (b)(4) repackaged Avastin syringes back (no documentation of the return). A total of (b)(4) patient-specific repackaged Avastin syringes were administered to patients. Your quality unit failed to follow up with the patients.

f) Lot # 150119R (batch size of (b)(4) made on 1/19/15 and Lot 150116B (batch size of (b)(4)) made on 01/16/15 were released and shipped prior to receiving the sterility test results. Both lots were reported to be non-sterile by the CTL. For both lots, your quality unit failed to conduct a root cause investigation and instead conducted a recall.

g) Lot # 150904J made on 9/4/15, Lot # 150508Z made on 5/8/15 and Lot # 150812C made on 8/12/15 were reported to be non-sterile by the CTL. For all lots your quality unit failed to conduct a root cause investigation.

5. Procedures for handling complaints were not followed.
Specifically, your firm failed to follow Job Aid QS 2.2: "How to Document and Report a Patient Complaint" (job aid was never approved by the Quality Unit) as it states to research the root cause of the complaint as necessary and record the results of the investigation. In addition, your firm failed to provide instructions within the Job Aid

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on how to report complaints that represent serious and unexpected adverse drug experiences to the FDA. Your firm failed to investigate the following unexpected adverse drug experiences:

a) In July 2015, your firm received a complaint for Lot # 150710A regarding two patients experiencing blurry vision after being administered the repackaged Avastin injection by the doctor. On 3/26/15, your firm received a complaint from a doctor's office regarding two patients experiencing eye infections after being administered the repackaged Avastin injections. Your quality unit failed to conduct investigations for these product complaints. In addition, your firm cannot trace a specific lot back to a particular patient. Instead, your firm can only trace which lots were shipped to the doctor's office. The doctor received the following lots 150129H, 150129I and 150129Q, but it is unclear which lot was administered to the two patients that were affected.

b) Since registering as a 503(b) facility on 9/21/15 your firm has received 68 consumer complaints relating to the plunger not advancing, fibers found on the needle, etc. These complaints have never been reviewed or investigated by the quality unit. Your firm's current practice for receiving complaints is through the Customer Service Representatives (CSRs) whose sole responsibility is replacing the implicated syringes. The CSRs then forward the complaints via email to the Quality Assurance Manager and Pharmacist in Charge. It was observed during the inspection that both the QA Manager and Pharmacist in Charge had consumer complaints within their emails for which they had not reviewed or investigated, one of which being the adverse drug experience regarding the eye infections received on 3/26/15. The Pharmacist in Charge stated the complaint files have not been adequately maintained and at the completion of monthly Continuous Quality Improvement Meetings these records are discarded.

c) Since 1/5/15 your firm has received a total of 917 consumer complaints (for which only replacement syringes were sent to the doctors' offices) relating to a cloudy syringe, plunger not advancing, fibers found on the needles, under-filling of the repackaged Avastin, etc. Your firm has been aware of the complaint issues regarding the plunger not advancing since the 2009 (b) (4) Study which attributed the root cause as (b) (4) . Your firm has still not taken the appropriate corrective and preventative actions to address the issue. Since 1/5/15, your firm has received a total of 363 consumer complaints for the plunger not advancing. These complaints have never been reviewed or investigated by the quality unit.

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6. Results of stability testing are not used in determining expiration dates.
Specifically, your outsourcing facility lacked valid analytical and sterility data to support the 90-day beyond use date (BUD) assigned to repackaged syringes of preservative-free Avastin (Bevacizumab) (b) (4) . According to your firm's Pharmacist in Charge/QA, the BUD was based on three (3) articles published in scientific journals. However, this information is not specific to your firm's operations. As per Job Aid SE 1: "Stability and Beyond Use Dating," your firm has ongoing stability studies of (b) (4)

7. Procedures describing the role and responsibilities of the quality control unit have not been adequately established and followed. Specifically, the Pharmacist-in-Charge/QA and the Quality Assurance Manager were uncertain about their duties and responsibilities regarding complaint handling, deviation investigations, adverse event investigation and reporting, documentation practices, adherence to written procedures, batch record and label review, cleaning procedures, personnel training, and performance of adequate media fills among other duties.

8. Batch records for re-packaged Avastin do not provide complete documentation of production of each batch of drug product. The actual batch yield is not documented and compared to the theoretical yield. As a result, your outsourcing facility was unable to maintain accurate accountability of syringes filled for each batch.

9. Your outsourcing facility was unable to identify which batch of Avastin was dispensed to each patient due to specimens of patient-specific labels not being maintained within the batch record.

10. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A)&(B). Specifically, the following information is not found on your drug product labels:

a) The statements "This is a compounded drug" and "Not for resale".
Examples of drug product labels that do not contain this information:
- Buprenorphine HCL (Grape) 8 mg Troche
- Linaclotide 75mcg/ml suspension
- Imiquimod/Deoxy-D-Glucose/EGCG/Salicyclic Acid 5%/1%/1%/10% Cream
- Metronidazole/Oxymetazoline/Niacinamide 1%/0.075%/4% Cream
- Minoxidil/Salicylic Acid 5%/2% Solution

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b) The date that the drug was compounded, storage and handling instructions, and list of active and inactive ingredients are not found on your product labels.
Examples of drug products labels that do not contain this information:
- Buprenorphine HCL (Grape) 8 mg Troche
- Linaclotide 75mcg/ml suspension
- Imiquimod/Deoxy-D-Glucose/EGCG/Salicyclic Acid 5%/1%/1%/10% Cream
- Metronidazole/Oxymetazoline/Niacinamide 1%/0.075%/4% Cream
- Minoxidil/Salicylic Acid 5%/2% Solution

c) Furthermore, the following information is not found on the container labels for the drug products you produce:
Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.
Examples of container labels that do not contain this information:
- Buprenorphine HCL (Grape) 8 mg Troche
- Linaclotide 75mcg/ml suspension
- Imiquimod/Deoxy-D-Glucose/EGCG/Salicyclic Acid 5%/1%/1%/10% Cream
- Metronidazole/Oxymetazoline/Niacinamide 1%/0.075%/4% Cream
- Minoxidil/Salicylic Acid 5%/2% Solution

11. Your outsourcing facility did not submit a product report to FDA identifying a product compounded during the previous six months prior to registration on 9/21/15 as required by section 503B(b)(2)(A). Specifically, the following products were compounded or repackaged between 3/21/15 and 9/21/15 but were not identified on your report dated 12/4/2015:

a) Avastin 1.25 mg/Dexamethasone 800mcg injectable
b) Methacholine Inhalation Solution
c) Non-sterile compounded drug products include but are not limited to:
- Buprenorphine HCL (Grape) 8 mg Troche
- Linaclotide 75mcg/ml suspension
- Imiquimod/Deoxy-D-Glucose/EGCG/Salicyclic Acid 5%/1%/1%/10% Cream
- Metronidazole/Oxymetazoline/Niacinamide 1%/0.075%/4% Cream

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Jessica L. Pressley, Drug Investigator CAPT Ileana Barreto-Pettit, Drug Investigator	01/21/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	1/12-15/2016 & 1/21/16
	FEI NUMBER 3012034698

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mark L. Sangree, President

FIRM NAME	STREET ADDRESS
Pacifico National Inc. dba Amex Pharmacy	1515 Elizabeth Street, Suite J
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Melbourne, FL 32901	Outsourcing Facility

- Minoxidil/Salicylic Acid 5%/2% Solution

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jessica L. Pressley CAPT Ileana Barreto-Pettit	Jessica L. Pressley, Drug Investigator CAPT Ileana Barreto-Pettit, Drug Investigator	01/21/2016

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."