DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

April 9, 2013

Mr. James Nahill
Owner
Pallimed Solutions, Inc.
400 West Cummings Park, Suite 1050
Woburn, MA 01801

Dear Mr. Nahill:

This letter is to inform you of an amendment made to the List of Inspectional Observations, FDA Form 483, issued on 03/29/2013 at the conclusion of an inspection of Pallimed Solutions, Inc. located in Woburn, Massachusetts. The amended FDA 483 includes additional deficiencies observed during the inspection that were discussed with you. These deficiencies were also discussed with you during our phone conversation on 04/09/2013. The amended FDA 483 has been enclosed with this letter, as well as a copy of the original FDA 483 issued on 03/29/2013.

Should you have any further question regarding this matter, please feel free to contact myself or Supervisory Consumer Safety Officer, Margaret Sands at One Montvale Avenue 4th floor, Stoneham, Massachusetts, (781) 587-7500.

Sincerely,

Ramon E. Martinez
Investigator
New England District Office

Enclosed

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax: (781) 587-7556 Industry Information: www.fda.gov/oc/industry	03/20/2013 - 04/09/2013* FEI NUMBER 3010084286

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James Nahill, Owner

FIRM NAME	STREET ADDRESS
Pallimed Solutions, Inc.	400 W Cummings Park, Suite 1050
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woburn, MA 01801-6519	Sterile Drug Product Producer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations. and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. The firm has failed to investigate the source of filamentous material observed in several lots of sterile injectable drug products. Specifically, on 03/22/2013, approximately fifty six (56) vials were observed to contain what appeared to be visible particulates (e.g. white filamentous material and black floaters) in the following sterile drug product lots intended for patient use:

Product Name	Lot Number	Number of vials observed with visible particulates
Alprostadil in NS 40MCG/ML Injectable	01222013@14	4 vials
DMSO Aqueous 50% Irrigation (200mL)	03122013@19	2 vials
BIMIX 30MG/1MG/ML Injectable	02252013@3	5 vials
Bacteriostatic Water	01072013@28	39 vials
TRIMIX 20MCG/30MG/1MG/ML Injectable	12142012@5	2 vials

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Ramon E. Martinez, Investigator

DATE ISSUED: 04/09/2013

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TRIMIX (#8) 20MCG/30MG/2MG/ML Injectable	12112012@5	1 vial
TRIMIX (#5) 10MCG/30MG/1MG/ML Injectable	02192013@3	1 vial
BIMIX 30MG/0.5MG/ML Injectable	02152013@3	1 vial
BIMIX 30MG/2MG Injectable	12112012@2	1 vial

B. Deviation report (dated 12/14/2012) after foreign matter, described as brown floating particle was found in a vial of Bacteriostatic Water lot # 10242012@15. The firm never identified the type of contamination observed. According to the investigation, the rest of the lot was inspected to assure "there is nothing else growing". There is no documentation that this lot was rejected and not dispensed for patient use.

C. The firm failed to investigate observed defects including: shape and color variation and lack of size uniformity in lyophilized drug product vials of several lots of Human Chorionic Gonadotropin (HCG) Injection (e.g. 10042012@6) held at the firm intended for patient use.

OBSERVATION 2

Buildings used in the processing, packing, and holding of a drug product are not maintained in a good state of repair.

Specifically,

A. On 03/20/2013, a rip in the sleeve of the glove box used to product high risk sterile drug products was observed. An evaluation of potential microbial ingress was not conducted.

B. On 03/20/2013, cracks and chipped paint in the ceiling of the compounding room directly above the horizontal flow hood used for the preparation of sterile drugs was observed.

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OBSERVATION 3

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Laminar Flow Hood ((b) (4) hood) used in the preparation of sterile drug product was observed to contain what appeared to be yellow/brownish discoloration in the metal grid in front of the HEPA filters. During the inspection, a pharmacy technician was observed placing syringes at approximately 6 inches from the location of the yellow/brownish discoloration.

B. On 03/20/2013, I observed residue covering the clear plastic curtains used to divide the gowning area from the rest of the compounding room. These curtains come in direct contact with the technician's gown before engaging in sterile drug product producing activities.

OBSERVATION 4

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

Specifically,

Media Fills

A. The sterile technique qualifications/validations (media fills) does not represent routine operating conditions and does not evaluate worst-case activities that can provide a challenge to manual aseptic operations. Specifically,

i. The media fill does not challenge representative container closure systems currently used at the pharmacy. For example the firm performed the media fill studies using (b filled vials. However the firm's batch size can reach up to (b) vials of sterile drug product.

ii. The firm has not performed media fills for other container closures. For example: large volume vials, syringes, ophthalmic and nasal bottles used to fill sterile drug products (e.g. Vancomycin Ophthalmic Solution, and DMSO Irrigation Solution) for patient use.

iii. The firm has not simulated the lyophilization process (e.g. loading and unloading of partially stoppered drug product in a non classified area and sterile holding inside the lyophilizer unit) for Human Chorionic Gonadotropin (HCG) sterile drug product as part of their media fills.

iv. The media fills do not simulate aseptic manufacturing operations that incorporate worst-case activities and conditions that provide a challenge to aseptic operations. For example: maximum number of personnel and their activities, an evaluation of critical routine and non-routine interventions such as the continuous entering and exiting of the ISO 5 (class 100) laminar flow hoods used in the production of sterile drug products.

Sterile (b) (4)

B. Sterile (b) (4) has not been validated for its intended use. For example:

i. Bacterial retention challenge has not been performed for the product contact (b) (4) used to (b) (4) sterile injectable products intended for patient use for example: HCG and BIMIX. Also, there is no data to support that these (b) (4) are compatible with their respective drug product as evidenced by the foreign matter described as filamentous contamination found in ready to be dispensed sterile drug product vials.

ii. The (b) (4) is recommended to be used for research use only and not intended for *in-vitro* diagnostic or for parenteral use. There is no data to support that this (b) is integrity tested before use. This (b) (4) is used for the compounding of sterile Human Chorionic Gonadotropin (HCG) and Sermorelin Injectable drug products.

(b) (4) Sterilization

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Woburn, MA 01801-6519	Sterile Drug Product Producer

C. There is no data to support that the (b) (4) sterilization cycles used for sterile drug products and product contact equipment can render items sterile. For example:

i. There is no data to support that the (b) (4) [redacted] is effective for the sterilization of Testosterone Cypionate Injectable drug products.

ii. There is no data to support that the (b) (4) [redacted] is effective for the sterilization of product contact containers and closures (e.g. 10 mL clear and amber glass bottles) used to fill sterile drug product such as HGC and Testosterone Cypionate for patient use.

Furthermore, during the inspection the firm was not able to provide the identification of the biological indicator used for the sterilization of drug products and containers and closures.

OBSERVATION 5

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, there is no documentation or evidence to support that the lyophilization cycles used for Human Chorionic Gonadotropin (HCG) sterile drug product is effective and reproducible. Furthermore, there is no data to support that the interior of the (b) (4) [redacted] are sterilized before or after use.

OBSERVATION 6

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the firm applies expiration dating to all compounded sterile injectable products ranging from immediate to one year for non reconstituted drug product. The stability program lacks data to

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support the beyond use data (BUD) assigned to sterile products produced at the facility. The firm assigns a beyond use date to a stock solution that is not the final drug product intended for patient use.

For example,

A. The firm did a time study for Alprostadil 1000mcg/mL Stock Solution. However, there is no data to support the BUD of 90 days for the dispensed forms of Alprostadil 40mcg/mL in NS dispensed for patient use.

B. The firm did a time study for the Bacteriostatic Water solution for 14 days. However, there is no data to support the BUD of 180 days assigned to Bacteriostatic Water Solution lots dispensed for patient use.

C. The firm did a time study to verify the potency, the presence of bacterial endotoxin and sterility for BIMIX for approximately 30 days. However, the firm assigns a BUD of approximately 60 days after the compounding date.

Furthermore, there is no data to support that sterile drug products (e.g. Alprostadil and BIMIX) will maintain sterility after they are filled in multi-use vials.

OBSERVATION 7

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

The firm's environmental monitoring program is not adequate to evaluate the adequacy of the aseptic fill zones during the production of sterile drug products. Specifically,

A. Environmental monitoring of the ISO 5 laminar flow hoods in not performed in association with daily operations. Sterile drug products are aseptically manipulated in these hoods as part of daily operations. However, environmental monitoring for non-viable particulates, surfaces and viable particulates is performed approximately every (b) (4), in the ISO 5 hoods.

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B. The firm failed to perform environmental monitoring during the manual aseptic connections during the manual filling of sterile injectable drug products including BIMIX, TRIMIX and HCG.

C. Personnel monitoring is limited to the assessment of the pharmacy technician's fingers done only on a (b) (4) basis. Other critical areas such as sleeve, forehead, forearms, chest and shoulders are not monitored.

Furthermore, during the review of the limited environmental monitoring data it was noted that samples were incubated at temperatures outside the ones specified in the Environmental Monitoring procedure. For example samples were incubated at 38 C when temperature is specified between (b) (4) It was also noted that in some occasions no sample results were recorded. The firm has not determined if this practice will affect the validity of the environmental monitoring program.

The firm started a limited environmental monitoring program since June 2012. However the firm has been compounding sterile injectable drug products since 2007.

OBSERVATION 8

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, there is no data to support that the clear and amber vials and stoppers used as product contact containers and closures for sterile drug products such as HGC and Testosterone Cypionate are depyrogenated prior to use.

OBSERVATION 9

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, differential pressure is not continuously monitored and controlled between controlled areas. The firm does not monitor the pressure differential of the open-face laminar flow hood and glove box used in the compounding of sterile drug products. There are no visible or audible alarms to detect differential pressure when occurs.

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OBSERVATION 10

Clothing of personnel engaged in the processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

A. Gowning used to produce sterile drug product is inadequate for the following:

i. Personnel face mask and hair nets are not sterile.

ii. Personnel exposed skin (e.g. foreheads) were observed as part of their gowning procedures. Personnel were observed leaning forward inside the (b) (4) (ISO 5) during the compounding of sterile drug products.

OBSERVATION 11

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

Specifically, the firm has not performed air flow pattern studies "smoke studies" of the (b) (4) Laminar Flow Hood and Glove Box (ISO 5 environment) used in the production of sterile drug products. There is no data to assess the required air uniformity and the potential presence of turbulences and air eddies in the ISO 5 aseptic fill zones during dynamic conditions.

OBSERVATION 12

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between drug product containers, closures, and drug products and to prevent contamination.

Specifically,

A. The facility is not designed and there is not enough space to prevent the ingress of microbiological organism to the compounding room used in the production of sterile drug products. For example: the firm used (b) (4) in the production of HCG and

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Sermorelin drug products. Due to the lack of space, the lyophilizer units are place in an unclassified area facing the doorway of the ante room and compounding room (classified areas). Partially stoppered vials are filled in the compounding room and moved to the unclassified area to be loaded and unloaded in the freeze dryer units.

The firm has not assessed if this practice has the potential to impact the quality of the compounded sterile drug product.

B. The firm has not assessed the potential microbiological impact of installing a portable sink with a water source in the ante room. This is inadequate for the following reasons:

i. The firm's ante room and compounding room are located in the same space divided with plastic flexible curtains. The compounding room is used in the production of sterile drug products.

ii. The firm made two holes in the wall of the ante room to bring flexible tubing out of the room. These flexible tubing are used to introduce and remove water to be used in the sink.

iii. Pharmacy technicians perform gowning operations in the ante room, including the use of the sink before entering the compounding room.

OBSERVATION 13

The quality control unit lacks responsibility to reject all procedures or specifications impacting on the identity, strength, quality, and purity of drug products.

Specifically, the firm does not have a formal visual inspection program for sterile drug products compounded for patient use.

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FOOD AND DRUG ADMINISTRATION

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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."

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New England District Office One Montvale Avenue Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	03/20-22/2013, 03/29/2013 FEI NUMBER 3010084286

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FIRM NAME	STREET ADDRESS
Pallimed Solutions, Inc. d/b/a Pallimed Pharmacy	400 West Cummings Park suite 1050
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

1. On 03/22/2013, I observed approximately fifty six (56) vials to contain what appeared to be visible particulates (e.g. white filamentous material and black floaters) in the following sterile drug product lots intended for patient use:

Product Name	Lot Number	Number of vials observed with visible particulates
Alprostadil in NS 40MCG/ML Injectable	01222013@14	4 vials
DMSO Aqueous 50% Irrigation (200mL)	03122013@19	2 vials
BIMIX 30MG/1MG/ML Injectable	02252013@3	5 vials
Bacteriostatic Water	01072013@28	39 vials
TRIMIX 20MCG/30MG/1MG/ML Injectable	12142012@5	2 vials
TRIMIX (#8) 20MCG/30MG/2MG/ML Injectable	12112012@5	1 vial
TRIMIX (#5) 10MCG/30MG/1MG/ML Injectable	02192013@3	1 vial
BIMIX 30MG/0.5MG/ML Injectable	02152013@3	1 vial
BIMIX 30MG/2MG Injectable	12112012@2	1 vial

In addition, the firm did not adequately evaluate deviation report (dated 12/14/2012) after foreign matter, described as brown floating particle was found in a vial of Bacteriostatic Water lot # 10242012@15.

The firm has not evaluated the routine compounding operations for the source of the visible particulates, for example: the use of non-sterile face mask and hair nets, and exposed skin by the pharmacy technicians during the compounding process of sterile drug products. Neither root-cause analysis nor permanent corrective/preventive actions were identified or documented by the firm to avoid future occurrences of these incidents.

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

2. On 03/20/2013, I observed defects including: shape and colors variation and lack of size uniformity in lyophilized drug product vials of several lots of Human Chorionic Gonadotropin (HCG) Injection (e.g. 10042012@6) held at the firm intended for patient use. The firm provided no documentation or evidence to support that the lyophilization cycles used for HCG sterile drug product is effective. According to the firm, HCG is sterilized via (b) (4) using a (b) (4) (b) indicated for research use and not for in vitro diagnosis or parenteral products. Moreover the firm stated that this (b) is not integrity tested after the sterile (b) (4) is executed.

3. The conditions listed below were identified during the inspection in areas used for the preparation, filling and/or storage of sterile drug products.

   a. On 03/20/2013, I observed brown discoloration in the metal grid located in front of the HEPA filters in the horizontal laminar flow hood used for the preparation, and filling of sterile drug products.

   b. On 03/20/2013, I observed residue covering the white plastic curtains used to divide the gowning area from the rest of the compounding room. These curtains come in direct contact with the technician's gown before engaging in sterile drug product producing activities.

   c. On 03/20/2013, I observed a rip in the glove of the glove box used to product high risk sterile drug products. The firm has not evaluated the potential for microbial ingress.

   d. On 03/20/2013, I observed cracks and chipped paint in the ceiling of the compounding room directly above the horizontal flow hood used for the preparation of sterile drugs.

***Dates of Inspection**:

03/20/2013 (Wed), 03/21/2013 (Thu), 03/22/2013 (Fri), 03/29/2013 (Fri)

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