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 Tel. (407) 475-4700 Industry Information: www.fda.gov/oc/industry	7/18-7/22/11, 9/19-23/11 & 9/27/11
	FEI NUMBER 3008058540

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michel (nmi) Rizo, Director of Pharmacy & Owner

FIRM NAME	STREET ADDRESS
Infupharma, LLC	2013 Harding St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hollywood, FL 33020	Compounding Pharmacy

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) (WE) OBSERVED:

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

a) There was a failure to handle and store components and drug products at all times in a manner to prevent contamination. For example, between 9/23/10 and 7/11/11, single-use vials of Avastin® (bevacizumab) solution for intravenous infusion were frequently used as multiple-use vials during your firm's re-packaging operations into individual syringes for intraocular injection without taking into consideration the microbiological, physical and chemical stability of the opened vial of Avastin after the initial puncture. According to the package insert for Avastin, after opening the vial the manufacturer recommends to "discard any unused portion left in a vial, as the product contains no preservatives." However, your firm conducted the following repacking operations that were not in accordance with the manufacturer's recommendations for this drug product:

1) As per your statement on 7/19/11, two (2) vials of Avastin 4ml, lot # 879296 were received by your firm and were repackaged into 0.1 ml syringes on multiple days as follows:
   i) Lot 06212011 repackaged on 6/21/11: 16 syringes
   ii) Lot 07012011 repacked on 7/1/11: 4 syringes
   iii) Lot 07052011 repackaged on 7/5/11: 30 syringes
   iv) Lot 07062011 repackaged on 7/7/11: 15 syringes

These batches of repacked Avastin have been associated with twelve (12) reports of bacterial infections of the eye after intraocular administration.

2) An unknown quantity of Avastin 16ml vials, lot # 883496 was received by your firm and was repackaged into 0.1 ml syringes on multiple days as follows:
   i) Lot 07072011 repackaged on 07/07/11: 14 syringes
   ii) Lot 07082011 repackaged on 07/08/11: 7 syringes

Fourteen (14) unused syringes of the above mentioned lot 07072011, along with one (1) unopened vial of Avastin

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lot #883496 were sampled by FDA. An FDA lab analysis of the sample revealed microbiological growth in three (3) of the syringes.

b) Environmental monitoring of the Class 5 Laminar Flow Workbenches (LAFWs) and Biological Safety Cabinet (BSC), Class 7 buffer area, and Class 8 ante-area was not performed adequately and periodically according to a written program. For example,

1) Surface and "air" sampling of unspecified locations within the three LAFWs using the (b) (4) ™ kit was performed only on 1/29/10 and 5/2/11. According to the (b) (4) Log, the samples were incubated for an undocumented number of days at a temperature of 20-25°C, which is not in accordance with the (b) (4) manufacturer's instructions which require incubation at (b) (4) . The same media lot # (b) (4) was used for both tests (performed approximately sixteen (16) months apart) without documentation of the expiration date for the media and there were no positive controls. The negative results were approved by the pharmacist (b) (6), (b) (7)(C) on unspecified dates without noting the discrepancies. Furthermore, you firm did not follow your SOP "Sterile Admixture Quality Control" rev. 7/21/07, which states that (b) (4) (b) (4) (b) (4) However, environmental monitoring for low, medium and high risk sterile compounding areas has only been conducted twice since 1/29/2010.

2) Sampling of viable particles in the clean room was not conducted prior to 7/12/11. In addition, the report provided by the contractor did not specify the specific location where the air sample was obtained, the identification of the organisms found in the anteroom, and the final results of the air sampling for the Class 5 LAFWs. Furthermore, this test was not conducted in accordance to a written procedure approved by your firm.

3) Air pattern analysis via smoke studies of the two (2) Class 5 LAFWs and the BSC was not adequately conducted and documented to demonstrate proper unidirectional airflow under dynamic conditions. On 9/19/11, we observed the pharmacist (b) (6), (b) (7) leaning his upper body under the LAFW while conducting aseptic operations during the compounding process of Vancomycin, lot # 09192011.

c) On 9/19/11, we observed the pharmacist (b) (6), (b) (7)(C) wiping the top of the rubber stopper of Vancomycin vials with non-sterile (b) (4) pre-moistened prep pads immediately prior to puncture during the

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compounding process of Vancomycin, lot # 09192011. Furthermore, empty bottles of sterile (b) (4) are re-filled with non-sterile (b) (4) (intended for floor cleaning) without obliterating the label to prevent use of non-sterile (b) (4) in sterile compounding operations requiring sterile (b) (4)

d) The flow of components, drug product containers, closures, in-process materials through the pharmacy is not designed to prevent contamination and control the bioburden of components. For example, non-sterile components used in the high-risk compounding of the sterile Hydroxyprogesterone caproate (HPC) injection are weighed, mixed and heated in a non-classified area, i.e. the pharmacy hallway, by non-gowned and non-gloved personnel before being transferred to the Class 7 buffer area through a transfer window for further processing. In addition, you lacked bioburden limits for the non-sterile components used for the compounding of sterile preparations. Similarly, packaged compounding supplies and components are wiped down with non-sterile (b) (4) (b) (4) instead of sterile (b) (4) in the same uncontrolled area instead of the Class 8 ante-room prior to the transfer to the Class 7 buffer area.

e) On 7/20/11, we observed an excessive amount of supplies and components in cartons in the Class 7 buffer area where the Class 5 LAFWs and BSC are located. On 9/19/11, we observed several electrical cords and surge protectors on the floor underneath the Class 5 LAFWs making it difficult to properly clean the floors with (b) (4) as used by your firm.

f) On 7/18/11, we reviewed your Quality Control Temperature Log and observed that the temperature was not recorded on 7/14/11 and 7/15/11. Similarly, we reviewed your Quality Control Pressure Differential Log for the clean room and observed that the differential pressure was not recorded for 7/12/11, 7/13/11, 7/14/11, and 7/15/11. On 7/15/11, your firm conducted high-risk compounding of Hydroxyprogesterone caproate (HPC) injection, lot # 07152011.

2. 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,

a) The aseptic repackaging processes of the Avastin and Human Chorionic Gonadotropin (HCG) injectables and the high-risk compounding process of Hydroxyprogesterone caproate (HPC) injectable were not validated through adequate (b) (4) media fills performed by all compounding personnel in accordance with a written program.

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For example, between 7/18/11 and 7/22/11, you stated on multiple occasions that you did not conduct media fills. However, upon resuming the inspection on 9/19/11, you provided two (2) (b) (4) M Logs which you identified as the media fill records. These records documented that media fills were conducted for low and medium-risk level compounding (not for high-risk) by three pharmacy technicians on separate dates as follows: 11/19/08 ((b) (6), (b) (7)), 7/8/09 ((b) (6), (b).), 1/29/10 (b) (6), (b) (7)(C) and 8/15/10 (b) (6), (b) (7)(C) As per your statement on 9/19/11, you are the only one currently authorized to perform aseptic operations but there is no documentation that you have conducted any media fills. Also, the media fill records documented incubation of samples at either 25°C or 35°C for an unknown number of days; however, your firm's unqualified incubator only has a handwritten setting on the temperature dial of 30°C. There was no documentation that the correct temperature was maintained and monitored during the incubation periods.

b) Your firm's sterilization processes by filtration with a (b) (4) filter, autoclaving (b) (4), or by (b) (4) have not been validated according to a written program. For example, the effectiveness of (b) (4) or (b) (4) sterilization was not verified by using appropriate biological indicators and other confirmation methods such as temperature-sensing devices. In addition, the suitability of the (b) (4) (b) (4) filter (Product code: (b) (4)) used for the filtration of different aqueous and oily preparations was not established and documented.

Moreover, you had two formulation instructions for the high-risk compounding of HPC injectable which differed in the temperature and length of the sterilization process by (b) (4) of the compound filled in vials. One formulation required a temperature of (b) (4) for (b) (4) hours and the other required a temperature of (b) (4) for (b) (4) hour. You lacked data to demonstrate that both methods were equally effective in sterilizing without affecting the stability and quality of the compound. Furthermore, you lacked documentation showing which method was used by your firm.

c) The effectiveness of the (b) (4) depyrogenation cycle for glassware, e.g. vials, was not conducted according to a written program incorporating the use of endotoxin challenge vials to verify that the cycle is capable of achieving a 3-log reduction in endotoxin. In addition, there was no documentation of the depyrogenation of vials used in your aseptic process for HPC.

3. Employees are not trained and qualified on proper garbing practices and aseptic techniques prior to performing aseptic compounding operations. Specifically,

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a) Compounding personnel, i.e. the pharmacists and pharmacy technicians, were not properly qualified on aseptic techniques by providing training, evaluating their competency in garbing and gloving procedures, performing media fills of high-risk preparations, and conducting glove fingertip sampling before being allowed to compound sterile preparations for human and veterinary use. According to your SOP "Sterile Admixture Quality Control" rev. 7/21/07, (b) (4)

(b) (4)

(b) (4) You stated that your firm does not perform any gloved fingertip sampling.

b) On 7/19/11, during a mock demonstration of the repackaging process of Avastin injectable in the Class 5 Biological Safety Cabinet, we observed the Pharmacy Technician (b) (6), (b) (7)(C) use non-sterile gloves when handling sterile supplies and products.

c) On 9/19/11, we observed the compounding process of Vancomycin lot # 09192011 by the pharmacist (b) (6), (b) (7)(C).) and noted the following deficiencies:

1) The pharmacist removed his non-dedicated shoes prior to entering the ante-area, walked in his socks in the ante-area which lacked demarcation of dirty and clean areas, and donned his shoe covers over his socks in the same area he had previously walked in socks.

2) He did not properly wash his hands and forearms with an approved disinfectant prior to donning his gown. He washed his hands after donning his gown and dried them with kitchen-grade paper towels, which are not designed to prevent particulate shedding.

3) He sanitized his hands by using a water-based (b) (4) Hand-Sanitizer instead of an alcohol-based hand scrub.

4) The gown worn by the pharmacist was too small thus exposing his backside and wrist area. We observed a ~1" gap of exposed skin between the pharmacist's gloves and gown sleeves while performing aseptic operations in the Class 5 LAFW.

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5) During the compounding process, we observed him leaning his upper body under the LAFW while conducting aseptic operations.

d) On 9/19/11, we observed the pharmacy technician (b) (6), (b) (7)(C) inside the clean room performing a mock demonstration of the (b) (4) test in the Class 5 LAFW. Her hairnet only covered her head and not the ~15" pony tail which was exposed to the environment.

4. Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing. Specifically,

a) Units of HPC 250mg/mL oil injectable drug product which are manufactured in batches of approximately (b) (4) (b) (4) are routinely released about five (5) days after compounding prior to the completion of the (b) (4)-day sterility test. Furthermore, no bacterial endotoxin (pyrogen) testing is conducted for this product. HPC injectable is administered to pregnant women at risk of pre-term delivery.

b) Avastin® 100mg/4-mL single-use vials for infusion repacked into individual syringes for intraocular injection are not tested for conformity with microbiological specifications prior to release.

5. Drug products failing to meet established specifications are not rejected. Specifically, Hydroxyprogesterone caproate (HPC) 250-mg/mL, batch # 03012011@07 compounded as a high-risk preparation on 3/1/11 had an out-of-specification result of 75.9% (spec: (b) (4)) for assay (potency) on 3/10/11. As per your verbal statement on 9/27/11, in order to achieve the desired concentration of 250mg, your firm re-packed (for the second time) the pre-filled single-use 1mL syringes into new syringes on 3/22/11 under batch # 03222011, and changed the fill volume from 1mL to 1.3 mL. Your firm lacked scientific data to demonstrate that this additional manipulation did not affect the safety, quality, and purity of this compounded drug product. Furthermore, your firm lacked documentation that a second re-packing operation occurred and did not test the repacked 1.3 mL syringes for sterility and potency before releasing them for administration to pregnant patients at risk for pre-term delivery.

6. Initial qualification and routine calibration, maintenance and cleaning of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance. Specifically,

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a) The (b) (4) Oven used to depyrogenate glass vials and to sterilize filled 20-cc glass vials of HPC has not been qualified, maintained or cleaned according to a written program.

b) The (b) (4) Fully Automatic Autoclave used for the sterilization of all aqueous injectable solutions and rubber stoppers has not been qualified, maintained or cleaned according to a written program. In addition, the programmed sterilization cycles have not been validated and the thermometer has not been calibrated against an NIST standard.

c) The (b) (4) bench-top incubator used for the incubation of media fills and environmental monitoring samples has not been qualified, maintained or cleaned according to a written program. Visual inspection of the incubator showed a ~ ¼" gap between the door and the chamber when closed and the temperature dial only showed a single handwritten setting of 30°C.

d) The (b) (4) analytical balance model (b) (4) used to weigh all components for compounding lacked calibration records for the most recent calibration performed by a contractor on 8/4/11. In addition, there was no documentation demonstrating the minimum weight that could be accurately weighed on this balance. Furthermore, daily checks with certified weights are not conducted.

e) All thermometers used in the refrigerator, incubator, autoclave, and compounding processes lacked calibrations against an NIST-standard. The temperatures of your refrigerator and freezer used to store components and finished drug products are not monitored daily to ensure that proper storage conditions are maintained.

f) The magnehelic gauges used to measure differential pressure between areas in the clean room lacked calibration records.

g) According to your SOP "Laminar Airflow Hoods," revision 5/14/2008, "A copy of the operating manual for the hoods should be available to all employees trained in aseptic manipulations." On 9/21/11, when we requested the manuals for the LAFWs, autoclave, incubator, and convection oven, the pharmacist (b) (6), (b) (7)(C)) stated that there were not readily available and that it would take seventy-two (72) hours to provide them.

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

a) There are two different written procedures for handling complaints neither of which are followed by your firm.

b) As per your statement on 9/21/11 you received two (2) complaints from two (2) different sources regarding the adverse effects, i.e. eye infections, experienced by some patients that received Avastin intraocular injections. However, as of 9/21/11, the complaints had not been logged and there was no documentation of an investigation being conducted as per your SOPs.

8. Procedures describing in sufficient detail the controls employed for the issuance and verification of labeling are not written and followed to ensure all information is complete and accurate. For example,

a) The immediate label for HPC 17P 250-mg/mL injectable, lot # 06152011 which was compounded on 6/15/11 had a Beyond-Use-Date (BUD) of 6 months (12/15/11), whereas the compounding record showed a BUD of 120 days (10/13/11), and the formulation record showed a BUD of 90 days (9/15/11). The error in the BUD on the label was detected during the inspection and not prior to release and distribution of this batch. Both pharmacists (b) (6), (b) (7)(C) stated that they did not know how to change the BUDs in their (b) (4) Database system used to generate compounding records and labels.

b) The compounding record and label approved by the pharmacist on 9/19/11 for Vancomycin lot # 09192011 showed a BUD of 10/17/2011(28 days); however, the pharmacist ((b) (6), (b) (7).) had stated that the BUD was 14 days as stated in the Handbook on Injectable Drugs, 15th edition. The discrepancy in BUD was not detected by the pharmacist until pointed out during the inspection.

c) When the formulation of Hydroxyprogesterone caproate 250-mg/mL oil injection solution was changed from castor oil to sesame oil, there was no evaluation of the need to revise the product label to declare the use of an allergen in the formulation.

9. There is no written testing program designed to assess the stability characteristics of drug products. Specifically, your firm lacked reliable stability data to support a beyond-use-date (BUD) of 30 days for Avastin

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repacked into 1-mL syringes.

10. The Compounding/Logged Formula Worksheets records do not include complete and accurate information relating to the compounding and control of each batch. Specifically,

a) Sterilization by (b) (4) or (b) (4) including settings, cycles, temperature and time is not documented. Print-outs from the autoclave showing temperature and time are not reviewed and maintained with the compounding record.

b) Integrity testing of the (b) (4) sterilizing filter by (b) (4) test or equivalent test recommended by the manufacturer is not documented after compounding operations.

c) Number of containers, i.e. syringes and vials, filled per batch is not documented on the compounding or repackaging record.

d) The Avastin Logged Formula Worksheet provided by the firm includes a "Date made" sub-heading. Although this subheading was intended to be reflective of the date on which the Avastin was repacked, the pharmacist (b) (6), (b) (.) explained that in some cases this date is representative of the date on which the record was printed, and not the date on which the Avastin was repacked. For example, he explained that the Avastin record with a "Date made" of 6/21/11 was actually repacked on 6/22/11. He also said that the Avastin record with a "Date made" of 7/1/11 was actually repacked on 7/5/11. These discrepancies were not corrected on the record by the pharmacist before release of the drug product.

e) Compounding/repackaging batch records are not always created and reviewed prior to compounding operations. For example, Lot 07062011 of Avastin 2.5mg/0.1-mL Injectable was repackaged on 7/6/11 as per the label affixed to the Logged Formula Worksheet and your verbal statement on 7/20/11; however, the Logged Formula Worksheet documented the "Date Made" as 7/7/2011 and the "Date Entered" and "Date Modified" as 7/7/11. These discrepancies were not identified or corrected prior to the inspection.

f) On 7/19/11, during a mock demonstration of the repackaging process of Avastin injectable, we observed the Pharmacy Technician use a Mini Transfer Device for aliquot purposes. The step involving the Mini Transfer Device is not included in the Avastin compounding/repackaging record.

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11. Written procedures for cleaning and maintenance fail to include assignment of responsibility, maintenance and cleaning schedules, and a description in sufficient detail of methods, equipment and materials used. Specifically,

a) After the initiation of the inspection, sponge mops for the clean room floors were replaced with a mop equipped with replaceable non-shedding covers; however, written procedures have not been written and established to describe proper mopping practices and frequency to replace the covers.

b) Household bleach was replaced with non-sterile (b) (4) as the cleaning agent for daily mopping of the floor in the clean room without evaluating the suitability of (b) (4) as a daily cleaning agent for vinyl flooring.

c) On 7/19/11, we observed the Pharmacy Technician spray alcohol on the walls of the hood and then put her head under the hood to wipe the sprayed area.

12. Written procedures are not established and followed for the receipt, identification, storage, handling, approval and rejection of components and drug products. Specifically, your firm lacked written procedures for the acceptance of components and finished products for compounding and repacking operations. Certificates of Analysis (COAs) for all compounding components and finished products received were not filed and/or signed as reviewed. Requested COAs were obtained from the supplier's website and printed upon our request during the inspection. There is no documentation that the pharmacist verifies the identity and quality of the components prior to use in compounding operations.

13. Written distribution procedures are not followed. Specifically, on 9/21/11 you stated that you did not have agreements with delivery carriers or b4 or any other controls for the safe and appropriate transportation and delivery of compounded pharmaceuticals to ensure they are held under adequate conditions that would not affect the safety and quality of the drug. You failed to follow your SOP "Delivery of Pharmaceuticals & Ancillaries," rev. 12/3/07 which requires specific controls for the transportation and delivery of pharmaceuticals to the patient.

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