

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 02/21/2014 - 03/07/2014*
	<small>FBI NUMBER</small> 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Benjamin H. David, President

<small>FIRM NAME</small> Wells Pharmacy Network LLC	<small>STREET ADDRESS</small> 1210 SW 33rd Ave
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Ocala, FL 34474-2853	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drugs

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

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

Specifically,

The media fills associated with operator qualification for sterile product compounding personnel are inadequate. Some deficiencies include but are not limited to:

- A. The media fills associated with initial operator qualification for sterile product compounding personnel do not incorporate worst case conditions such as longer process times, most complex process, extended exposure of components, interruptions/breaks, or other applicable routine situations that could potentially impact the sterility of the product.
- B. Growth promotion tests are not conducted on the media used for media fills.
- C. Environmental monitoring and fingertip sampling was not conducted during media fills.

This is a repeat observation and was listed as Observation 2 on the FDA 483 dated 07/26/13.

OBSERVATION 2

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

Specifically, the most recent qualification of the ISO 7 cleanroom and the ISO 5 laminar air flow hoods completed on 12/13/13 by a contractor was not performed under dynamic conditions. In addition, the smoke studies completed on 12/13/13 in the ISO 5 LAFW were reported as acceptable, but were not recorded to verify the adequacy of the laminar air flow and did not document that they were conducted under dynamic conditions. Firm personnel confirmed that employees did not participate during the performance of the smoke studies.

This is a repeat observation and was listed as Observation 7 on the FDA 483 dated 07/26/13.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Nicole E. Knowlton, Investigator <i>N Knowlton</i> Gene R. Gunn, Investigator <i>GR Gunn</i>	<small>DATE ISSUED</small> 03/07/2014
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OBSERVATION 3

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

Specifically,

- A. No environmental monitoring was conducted between 07/27-09/15/13 and 12/18/13-02/04/2014. During this time period your firm produced lots of Avastin finished product syringes that were distributed.
- B. You are not conducting, at least on a daily basis, surface and air monitoring if the ISO 5 LAFW, despite production of sterile drug products.
- C. You are not conducting, at least on a daily basis, personnel monitoring, including fingertip sampling, of operators involved in sterile operations of sterile drug products in the ISO-5 LAFW.
- D. Growth promotion testing is not performed for the TSA and SDA media used for your firm's environmental monitoring program to ensure that it promotes growth of gram positive and gram negative bacteria, yeast and molds.

This is a repeat observation and was listed as Observation 5 on the FDA 483 dated 07/26/13.

OBSERVATION 4

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

Specifically, the suitability, efficacy, and limitations of disinfecting agents have not been assessed to ensure potential contaminants are adequately removed from surfaces in the ISO classified areas.

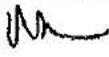
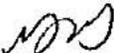
This is a repeat observation and was listed as Observation 6 on the FDA 483 dated 07/26/13.

OBSERVATION 5

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

Specifically, the Avastin finished product syringes produced by your firm have not undergone microbiological method suitability testing for finished product release testing. Additionally, your firm is not testing the Avastin finished product syringes for endotoxins.

This is a repeat observation and was listed as Observation 10 on the FDA 483 dated 07/26/13.

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OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm lacks written procedures for a stability program and reliable analytical data to support the 90 day beyond-use date assigned to the Avastin finished product syringes that your firm repackages. You solely rely on scientific literature to establish beyond-use dates for Avastin and there is no assurance, with the lack of scientific data, that your Avastin finished product syringes will remain sterile or maintain potency throughout the expiry period. The following is an example of the beyond-use dates assigned:

Avastin, 31G 0.05 ML Syringe, Lot #11012013@67 was assigned a 90 day beyond-use date of January 30, 2014
Avastin, 31G 0.05 ML Syringe, Lot #11222013@66 was assigned a 90 day beyond-use date of February 20, 2014

This is a repeat observation and was listed as Observation 8 on the FDA 483 dated 07/26/13.

OBSERVATION 7

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

Specifically, I observed the gowns worn by personnel engaged in the processing of sterile drug products in the ISO 5 laminar flow hoods were not sterile. Additionally, I observed firm personnel hang their gowns on a hanger in the anteroom for reuse in the sterile compounding area. Firm personnel confirmed that they do not purchase sterile gowns and that they reuse gowns in the sterile compounding area.

This is a repeat observation and was listed as Observation 3 on the FDA 483 dated 07/26/13.

OBSERVATION 8

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

Specifically, there is no written protocol or documentation available to demonstrate the [REDACTED] (b) (4) has been initially qualified to demonstrate the instrument is maintaining required limits for accuracy and precision. This instrument was used for finished product release of your sterile compounded products and specifically, the following lots of Avastin produced during the time frame of 09/11-12/30/13: 09112013@48, 09172013@72, 09242013@52, 09302013@83, 10012013@15, 10082013@25, 10172013@32, 10242013@59, 10282013@93, 10312013@36, 11012013@67, 11042013@87, 11062013@36, and 12102013@118.

OBSERVATION 9

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically, you have not documented all of the complaints your firm has received regarding your preparation containing

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Avastin. On 02/21/2014, firm personnel stated that approximately one week ago you were informed by a physician of a patient with an eye infection possibly caused by your preparation containing Avastin, which your pharmacy personnel had prepared and dispensed. As of 02/27/2014, the complaint was not logged and your firm did not have documentation of a complaint investigation.

Your firm had received two earlier complaints regarding your preparation containing Avastin. The complaint received 12/18/2013 reported the patient received a staph-like infection. The complaint received 01/14/2014 reported a case of endophthalmitis in one patient.

OBSERVATION 10

Investigations of did not extend to other batches of the same drug product.

Specifically, your firm has not investigated and determined the root cause for the following three complaints related to your Avastin preparations:

- A. On 12/18/2013, your firm received a complaint that a patient received a staph-like infection after an injection from Master Lot #11222013@66
- B. On 01/14/2014, your firm received a report of a patient with a case of endophthalmitis after an injection from Master Lot #11222013@66
- C. Your firm's personnel stated that you received a complaint in mid-February 2014 regarding an eye infection.

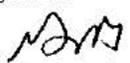
No records were provided to demonstrate that a root cause was determined, an investigation was conducted, or if it was determined whether any other batches were affected.

OBSERVATION 11

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, the Magnehelic gauges, #1 and #2, used to monitor the pressure differentials for your ISO classified areas lacked current calibration records and were due for calibration 12/31/13. The following lots of Avastin finished product syringes were produced after 12/31/13:
01082014@5, 01132014@12, 01152014@75, 01202014@9, 01222014@33, 01272014@69, 02042014@46, 02062014@62, 02182014@6, and 02192014@31.

This is a repeat observation and was listed as Observation 11 on the FDA 483 dated 07/26/13.

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*** DATES OF INSPECTION:**
 02/21/2014(Fri), 02/24/2014(Mon), 02/25/2014(Tue), 02/26/2014(Wed), 02/27/2014(Thu), 03/07/2014(Fri)

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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."