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 Industry Information: www.fda.gov/oc/industry	07/22/2013 - 07/26/2013
	FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Benjamin H. David, CEO & President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-5138	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 do not include adequate validation of the sterilization process.

Specifically,

a) The [redacted] (b) (4) tests conducted to verify the integrity of the sterilizing [redacted] (b) (4) used to [redacted] (b) (4) large volume batches have not been conducted properly and have failed integrity testing as recorded in the batch worksheets of sterile veterinary drug products such as Acetyl-D glucosamine injectable and Pentosan soldium polysulfate injectable.

The [redacted] (b) (4) test observed on 7/24/13 for the [redacted] (b) (4) used to sterilize Pentosan sodium polysulfate 250 mg/ml (Vet) injectable, lot 07242013@24 was not conducted properly in that the [redacted] (b) (4) was not [redacted] (b) (4) as required, the [redacted] (b) (4) was initially set at [redacted] (b) (4) and a [redacted] (b) (4) of [redacted] (b) (4) was observed immediately. This result was reported as passing "35" without determining the lowest [redacted] (b) (4) that would have produced [redacted] (b) (4) [redacted] (b) (4) in order to properly verify the integrity of the [redacted] (b) (4) A review of the manufacturer's specification sheet for the minimum [redacted] (b) (4) test disclosed a value of [redacted] (b) (4) and not [redacted] (b) (4) Therefore, this [redacted] (b) (4) did not pass integrity testing but was accepted as passing. A review of additional worksheets for other batches showed identical failing results of [redacted] (b) (4) for the [redacted] (b) (4) tests conducted for this [redacted] (b) (4)

b) Your firm failed to validate the various [redacted] (b) (4) used to sterilize products produced by your firm from non-sterile components. In addition, you failed to establish [redacted] (b) (4) bioburden limits in order to determine if it exceeds the maximum retention capability of the [redacted] (b) (4) For example,

a. The Certificate of Analysis (COA) received by your firm for the component Procaine HCL, the active ingredient in your finished drug product Procaine HCL P.F. 1% lot# 05242013@33 dispensed on 4/4/2013 does not contain a specification for bacteria, yeast or mold. Your firm receives this product without establishing a specification for bioburden.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	CDR Ileana Barreto-Pettit, Investigator Carla A. Norris, Compliance Officer LCDR Randall L. Morris, Investigator	07/26/2013

b. The COA received by your firm for the component Calcium Gluconate USP anhydrous powder has established specifications for yeasts, molds, total plate count and the objectionable organism Salmonella; however, your firm has not verified that the specification cited by the vendor is adequate for your product.

c) Your firm continues to use four (4) different types of [redacted] (Catalog numbers [redacted]) for sterilizing injectable drug products despite the statement on the [redacted] Certificate of Quality that "[redacted]" and an email dated 2/19/13 from the [redacted] manufacturer stating that these [redacted] have not been certified for use in parenterals and a suitable [redacted] test method has not been identified for these [redacted]. For example, the following batches of sterile injectable human and veterinary drug products were [redacted] with a [redacted]:

1) Nandrolone Decanoate (Human) 200mg/ml injectable, lot 06142013@9, produced on 6/14/13 was [redacted], and no [redacted] test result or other suitable [redacted] integrity test was documented after use.

2) Amikacin Sulfate (Vet) PF 250mg/ml injectable, lot 04252013@23, produced on 4/25/13 was [redacted] and no [redacted] test result or other suitable [redacted] integrity test was documented after use.

3) Pentosan Sodium Polysulfate (Vet) 250mg/ml injectable, lot 06282013@35 produced on 6/28/13 was [redacted] and no bubble point test result or other suitable [redacted] integrity test was documented after use.

d) There is no anti-microbial effectiveness data for sterile drug products containing preservatives such as Methylparaben/Propylparaben, Benzyl Alcohol and Benzethonium Chloride. Some of these products include sterile veterinary drugs such as Medroxyprogesterone Acetate 200mg/ml injectable, Methocarbamol 100mg/ml injectable and Amikacin Sulfate 250mg/ml injectable.

e) The validation of the sterilization cycles conducted in the [redacted] were deficient for the following reasons:

1. The [redacted] Verification cycle for the [redacted] conducted on 1/24/2013 and 2/07/2013 is inadequate in that the cycle parameters [redacted] for 20 minutes for [redacted] and [redacted] for 20 minutes for [redacted] does not bracket the cycle parameters of use for the compounded products you [redacted] sterilize in these [redacted] For example: Procaine HCL P.F. 1% injectable formulary worksheet provides for [redacted].

2. The verification cycle data does not include load parameters that bracket the most difficult products or components that your firm uses for [redacted] sterilization as the data indicates the [redacted] verification was conducted empty.

3. The verification cycle data for [redacted] (b) (4) #011 and #012 documents that the [redacted] (b) (4) biological indicators used for the cycle were incubated at 35°C for 24 hours. The manufacturer's certificate states the required incubation is 55-60°C for a minimum of 24 hours.

4. On 1/24/2013 the incubator labeled as #011 failed the verification cycle at [redacted] (b) (4) for 20 minutes. There is no indication that an investigation or root cause was identified prior to changing the cycle parameter to [redacted] (b) (4) and repeating the test.

f) The [redacted] (b) (4) Verification Log (validation) for #052 dated 5/14/2013 used for the sterilization of product components that cannot be adequately [redacted] (b) (4) sterilized is deficient in that it only validated a temperature setting of 160°C for a period of two (2) hours. However, your firm produced the following products and used the [redacted] (b) (4) to sterilize it at different temperature parameters:

a. The Ophthalmic self-emulsifying Ointment lot # 06242013@34 and lot # 07052013@3 which contain [redacted] (b) (4) prepared per your firm's formulary worksheet includes parameters for sterilizing these components by [redacted] (b) (4). Your validation data did not support this cycle.

g) Your firm uses an in-house purified water system to wash vials and stoppers before they are sterilized and used to fill sterile drug products. However, your firm could not provide any scientific data to confirm that the water system is monitored, sampled and maintained on a schedule that demonstrates the water is not adding additional bioburden to the containers and closures prior to in-house sterilization and depyrogenation. In addition, your firm's formula worksheet that is printed as a batch record for the washing, sterilization and depyrogenation of the vials specifies "*all clean glassware and serum vials are rinsed with purified water.*" There is no data to demonstrate the water meets the specifications of "purified" water.

OBSERVATION 2

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

Specifically,

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

1) The media fills using sterile vials 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.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	07/22/2013 - 07/26/2013
	FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Benjamin H. David, CEO & President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-5138	Producer of Sterile Drugs

2) Growth promotion tests are not conducted on the media used for media fills.

3). Environmental monitoring and fingertip sampling was not conducted during media fills.

b) No microbiological data was provided to support the 30-day expiration date assigned to containers and closures (glass vials and rubber stoppers) that are sterilized and depyrogenated by your firm and used for sterile drug products.

OBSERVATION 3

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

Specifically, the gowns worn by personnel engaged in the processing of sterile drug products in the ISO 5 laminar air flow hoods are not sterile.

OBSERVATION 4

There is a failure to thoroughly review 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, your firm failed to thoroughly conduct an investigation and identify a root cause when out-of-specification (OOS) results were obtained for the following drug products:

a) Sterility failure: Medroxyprogesterone Acetate (Vet) 200 mg/ml injectable, lot 05152013@1 (1200 ml) produced on 5/15/13 and [redacted] (b) (4) failed the USP <71> sterility test on 6/5/13. The batch was rejected but the investigation did not include identification of the microorganism, review of the [redacted] (b) (4) sterilization cycle and equipment, and environmental monitoring data to properly conduct an investigation to determine the root cause of the contamination and take appropriate corrective and preventive action.

b) Potency failure: Stanozolol (Vet) 50 mg/ml injectable, lot 04022013@28, (800 ml) had an OOS potency result of 116% (spec: [redacted] (b) (4)) when tested at 2 months "extended analysis" on 6/11/13. No investigation was conducted and no action was taken with the distributed batch with a BUD of 7/1/13.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	CDR Ileana Barreto-Pettit, Investigator Carla A. Norris, Compliance Officer LCDR Randall L. Morris, Investigator	07/26/2013

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	07/22/2013 - 07/26/2013
	FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Benjamin H. David, CEO & President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-5138	Producer of Sterile Drugs

OBSERVATION 5

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

Specifically,

a) No environmental monitoring has been conducted between 4/30-6/3/13 and 6/19-7/25/13 due to the lack of plate availability. During this time frame your firm produced and distributed approximately (b) (4) lots of sterile products.

b) Surface and air monitoring of the IS0-5 classified laminar airflow workstations (LAFW) is not conducted at least daily, despite production of sterile drug products.

c) Personnel monitoring, including fingertip sampling, of operators involved in sterile operations of sterile drug products in the IS0-5 LAFW is not conducted at least daily.

d) Growth promotion testing is not performed for the (b) (4) and (b) (4) 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.

e) There is no written documentation to support the proper time or incubation temperatures for your environmental media incubation after sampling. Your raw data does not include time and temperature data for the incubation period.

f) Your firm failed to qualify the (b) (4) incubators that you maintain for your environmental monitoring program. In addition, the (b) thermometers located in incubators # 002 (b) (4) and #004 (b) (4) failed to have traceability or calibration records available, and the (b) (4) did not contain a thermometer that is traceable or calibrated to verify the internal temperature of the unit and you solely rely on the visual digital display of the incubator.

OBSERVATION 6

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 to ensure potential contaminants are adequately removed from surfaces in the ISO classified areas.

b) Routine cleaning procedures of the IS0-5 classified LAFW do not include the use of a qualified sporicidal cleaning agent at established frequencies. For example,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	CDR Ileana Barreto-Pettit, Investigator Carla A. Norris, Compliance Officer LCDR Randall L. Morris, Investigator	07/26/2013

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	07/22/2013 - 07/26/2013
	FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Benjamin H. David, CEO & President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-5138	Producer of Sterile Drugs

1. Your firm uses [redacted] (b) (4) for ISO5 classified areas to include the laminar air flow hood and equipment. These cleaning agents have not been demonstrated to be sporicidal.

2. Your firm uses [redacted] (b) (4) for the ISO-7 cleanroom floor. The manufacturer's instructions on the labeling indicate [redacted] (b) (4) has sporicidal properties if a contact time of ten (10) minutes is administered. However, your firm's SOP "Cleaning and Maintenance of the Clean Room Facility" does not indicate contact times for the cleaning agents used within the aseptic processing area.

OBSERVATION 7

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

Specifically,

a) The most recent qualification of the ISO 7 cleanroom and the ISO 5 laminar air flow hoods completed on 2/11/13 by a contractor after the renovation of the cleanroom was not performed under dynamic conditions. In addition, smoke studies 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 if they were conducted under dynamic conditions. Aseptic processing personnel stated that they did not participate during the performance of the smoke studies.

b) The design of the cleanroom or the settings for positive differential air pressure in the cleanroom and anteroom did not appear adequate as the doors leading to the anteroom and the ISO-7 cleanroom were observed cracked open about 2 inches outward every day of the inspection and could not be closed due to the positive air pressure coming from the cleanroom and anteroom.

OBSERVATION 8

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

Specifically,

a) Your firm lacked written procedures for a stability program and reliable analytical data to support the beyond-use dates (BUDs) assigned to your sterile drug products. For example,
   a. Polidocanol (Laureth-9) 5% injectable (human), lot 021220132@16 had a 6-month beyond-use-date (BUD) of 5/13/13 but no stability data;
   b. Methocarbamol (Vet) 100 mg/mL injectable, lot 04092013@40, had a BUD of 4 months and stability data of one lot to only support 90 days;

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	CDR Ileana Barreto-Pettit, Investigator Carla A. Norris, Compliance Officer LCDR Randall L. Morris, Investigator	07/26/2013

c. Acetyl-D-Glucosamine 20% injectable (Vet), lot 02122013@28, with a BUD of 6 months and stability data of one lot to only support 90 days;
d. Xylazine HCL (Vet) 100 mg/mL injectable, lot 05232013@34, with a BUD of 6 months and stability data to only support 30 days.

There is no assurance, with the lack of scientific data, that your sterile drug products will remain sterile or maintain potency throughout the expiry period. You solely rely on scientific literature, pharmacists' knowledge, or vendor supplied information to establish beyond use dates up to 180 days for sterile drug products.

b) Your firm lacked chemical and microbiological stability data to support the expiration dates assigned to the following stock solutions observed in the refrigerator and used to produce batches of other sterile drug products. For example,

1. Atropine sulfate PF 1 mg/ml (0.1%) injectable, lot 04182013@11 produced on 4/18/13 with an expiration date of 10/15/13 had no stability data to support this 180-day expiration date. This component was used in (b) (4) batches of Trimix with atropine (human) injectable of various strengths, including lot 07172013@42 with a BUD of 7/31/13.

2. Alprostadil (M) 500 mcg/ml injectable, lot 07012013@15 produced on 7/1/13 with an expiration date of 8/20/13 had no stability data to support this 7-week expiration date. This component was used in (b) (4) (b) (4) batches of Trimix injectable of various strengths, including lot 07112013@37 with a BUD of 7/25/13 and lot 07172013@42 with a BUD of 7/31/13.

OBSERVATION 9

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, each batch of sterile human and veterinary drug products prepared from non-sterile components and (b) (4) sterilized are not routinely tested for potency, sterility, and endotoxins prior to release. For example,

a) Medroxyprogesterone acetate (Vet) 200 mg/ml injectable, lot 06142013@11 produced on 6/14/13 with a BUD of 6 months was not tested for potency and endotoxin prior to release.
b) Amikacin Sulfate (Vet) PF 250 mg/ml injectable, lot 04252013@23 produced on 4/25/13 with a BUD of 90 days was not tested for potency and endotoxin prior to release.
c) Nandrolone Decanoate (Human) 200 mg/ml injectable, lot 06142013@9 produced on 6/14/13 with a BUD of 90 days was not tested for potency prior to release.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	07/22/2013 - 07/26/2013
	FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Benjamin H. David, CEO & President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-5138	Producer of Sterile Drugs

OBSERVATION 10

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

Specifically, none of the finished sterile drug products produced at your firm have undergone microbiological method suitability testing for finished product release testing conducted by a contract laboratory. The method suitability testing is required to demonstrate the drug product test samples do not inhibit growth in sterility test media for example.

OBSERVATION 11

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

Specifically,

a) The pressure gauge [redacted] (b) (4) used to measure the [redacted] (b) (4) to test the integrity of the [redacted] (b) (4) lacked calibration records and has not been maintained as per SOP 4.210 "Use and Maintenance of the [redacted] (b) (4) Integrity Tester."

b) The pressure gauge attached to the [redacted] (b) (4) tank used to conduct the [redacted] (b) (4) test of the [redacted] (b) (4) [redacted] (b) (4) lacked calibration records.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	CDR Ileana Barreto-Pettit, Investigator Carla A. Norris, Compliance Officer LCDR Randall L. Morris, Investigator	07/26/2013