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	05/30/2014 - 06/19/2014* FEI NUMBER 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Benjamin H. David, President

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network LLC	1210 SW 33rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-2853	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 I 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 used to qualify operators to perform sterile production do not include:
A. Growth promotion tests on the media used in media fills.
B. Environmental monitoring during fingertip sampling and media fills.

This is a repeat observation and was listed as Observation 1 on the FDA 483 dated 03/07/2014 and Observation 2 on the FDA 483 dated 07/26/2013.

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 does not include:
A. Performance under dynamic conditions.
B. Documentation of air flow studies (smoke studies) under the Laminar Air Flow Workstation where sterile products are processed.
C. Documentation to show that quality reviewed the qualification.

This is a repeat observation and was listed as Observation 2 on the FDA 483 dated 03/07/2014 and Observation 7 on the FDA 483 dated 07/26/2013.

OBSERVATION 3

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

Specifically,

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	Nicole E. Knowlton, Investigator	06/19/2014

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A. Surface and air monitoring of the ISO 5 Laminar Air Flow Workstation used in the production of sterile drugs is only conducted on a [redacted] (b) (4) basis and sterile drug products are prepared in these hoods [redacted] (b) (4).
B. Personnel monitoring, including fingertip sampling, of operators involved in daily sterile operations of processing sterile drug products in the ISO 5 LAFW is only conducted on a [redacted] (b) (4) basis.
C. Growth promotion testing is not performed for the [redacted] (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.

This is a repeat observation and was listed as Observation 3 on the FDA 483 dated 03/07/2014 and Observation 5 on the FDA 483 dated 07/26/2013.

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

This is a repeat observation and was listed as Observation 4 on the FDA 483 dated 03/07/2014 and Observation 6 on the FDA 483 dated 07/26/2013.

OBSERVATION 5

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

Specifically, the documentation you provided does not establish that a method validation was performed for the [redacted] (b) (4) instrument, [redacted] (b) (4), that you use for sterility testing for all of the sterile products produced at your firm, including but not limited to, Sermorelin Acetate products. Additionally, you have no documentation defining the results (events vs. microbe), the process for evaluating events, or documentation showing the evaluation of events when they do occur.

Firm management stated that you have conducted a side by side analysis with a contract lab as a part of the validation process; however this is limited to the comparison of one set of results for numerous different products. Additionally, you have not verified the reliability of the analytical results of the contract laboratory.

This is a repeat observation and was listed as Observation 5 on the FDA 483 dated 03/07/2014 and Observation 10 on the FDA 483 dated 07/26/2013.

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OBSERVATION 6

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, you have no written procedures or scientific data to ensure that the lyophilization cycle is appropriate for the Sermorelin Acetate finished products your firm produces.

A. Firm personnel explained the production process for Sermorelin Acetate/GHRP (2)-Lyophilized 9MG/3MG and stated that the lot is placed in the lyophilizer for [redacted] (b) (4) and after a visual inspection, if the powder does not appear to be dry, the lot remains in the lyophilizer longer.
B. The Director of Quality Assurance stated that the lyophilizer is programmed to reach the desired temperature and pressure and that no validation has been conducted regarding the process for the Sermorelin Acetate finished products.

OBSERVATION 7

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 scientific data to support the 180 day beyond-use date assigned to the Sermorelin Acetate finished products. The only data provided was a [redacted] (b) (4) study for one Sermorelin Acetate product, although you produce numerous different formulas. Firm personnel stated that you rely on scientific literature to establish beyond-use dates without actually conducting any studies.

Furthermore, 14 of the 17 Logged Formula Worksheets for Sermorelin Acetate reviewed contained two beyond-use dates which were conflicting. For example: 07/31/2014 and 07/28/2014 were both listed as the beyond-use date on your Logged Formula Worksheet for Sermorelin Acetate/GHRP (2) Lyophilzed 9mg/3mg Vial, Lot #01282014@48. Additionally, the label for the bottle of Semorelin Acetate 9mg, Lot #01282014-48 was assigned a Use By date of 07/2014.

For example: Sermorelin Acetate/GHRP (2) & (6) Lyophilized 9mg/3.15mg/3.15mg Vial, Lot 05122014@58, prepared on 05/12/2014, was assigned a 180 day beyond-use date of 11/08/2014.

This is a repeat observation and was listed as Observation 6 on the FDA 483 dated 03/07/2014 and Observation 8 on the FDA 483 dated 07/26/13.

OBSERVATION 8

The written stability program does not include testing of drug products for reconstitution after they are reconstituted.

Specifically, your firm lacks written procedures for a stability program and reliable scientific data to support the 180 day beyond-use date assigned to the Sermorelin Acetate finished products, once the product is reconstituted. Firm personnel

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stated that you rely on scientific literature to establish beyond-use dates without actually conducting any studies. Additionally, your firm does not assign a separate beyond-use date for the Sermorelin Acetate finished products that are to be reconstituted after they are dispensed.

OBSERVATION 9

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

Specifically, the gowns worn by operators engaged in processing of sterile drug products in the ISO 5 Laminar Air Flow Workstations are not purchased sterile and are not sterilized by the firm. Firm personnel confirmed that they do not purchase sterile gowns or sterilize the gowns worn, and that gowns are reused in aseptic processing. Your production employees wear these non-sterile gowns while conducting operations using the ISO 5 Laminar Air Flow Workstation (LAFW), which includes placing their gowned arms inside the working area of LAFW.

This is a repeat observation and was listed as Observation 7 on the FDA 483 dated 03/07/2014 and Observation 3 on the FDA 483 dated 07/26/2013.

OBSERVATION 10

The quality control unit lacks the responsibility and authority to approve and reject all drug products.

Specifically,

A. The Director of Quality Assurance stated that the release of finished drug product for shipment is conducted by the firm's Pharmacists, who are not part of the Quality Assurance Unit. The Quarantine Testing forms, covering 03/18-06/12/2014 and the Inhouse Quarantine Testing forms, covering 03/11-06/12/14, which your firm uses for finished product release, are initialed by the pharmacists.
B. The Quality Control Unit has not reviewed any of the Daily Control Record Sheets, since the [redacted] (b) (4) instrument [redacted] (b) (4), was installed 07/03/2013. These sheets document the system suitablity checks for the firm's inhouse [redacted] (b) (4) scanner used for testing and release of sterile products, including but not limited to, the Sermorelin Acetate products.

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Your firm does not document all batch related activities on the Logged Formula Worksheets for each batch prepared.

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A. The lyophilization process was not listed on 17 of the 17 Logged Formula Worksheets that were reviewed for the Lyophilzed Sermorelin Acetate products prepared by your firm. There were no other records available documenting the lyophilization process for these batches.
B. Four of the 17 Logged Formula Worksheets reviewed for the Sermorelin Acetate products prepared by your firm contained a handwritten number indicating the actual number of vials prepared, which contradicted the typed number documented on the Worksheet. I was unable to determine the actual batch yield for these lots. Firm personnel stated that the typed number for batch yield is not always the amount prepared.

OBSERVATION 12

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, for analytical test results, you rely on the Certificate of Analysis provided by your contract laboratory; however, you have not established the reliability of their analyses through either third party testing, on site audits, or any other means.

OBSERVATION 13

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

Specifically, your firm is not following your procedure, Complaint Handling SOP 5.030, Version 1, effective 10/01/2012 in that:

A. The complaint regarding Sermorelin Acetate/GHRP (2) received on 05/16/2014, remains open and was not closed out in the [redacted] (b) (4) time frame required by Section 9.5.2 of your SOP.
B. The full complaint investigation has not been documented regarding the Sermorelin Acetate/GHRP (2) complaint received on 05/16/2014 .
C. The Customer Complaint Record required by Section 9.4 of your SOP to document complaints is not used.
D. Complaint numbers are not assigned as required by Section 9.3 of your SOP.

This is a repeat observation and was listed as Observation 9 on the FDA 483 dated 03/07/2014.

*** DATES OF INSPECTION:**
05/30/2014(Fri), 06/03/2014(Tue), 06/09/2014(Mon), 06/10/2014(Tue), 06/13/2014(Fri), 06/19/2014(Thu)

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