DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/16/2018-4/27/2018* FEI NUMBER 3011761321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Angie C. Andrews, Director of Operations

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network, LLC	450 US Highway 51 Byp N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dyersburg, TN 38024-3655	Outsourcing Facility

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

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, your Quality Unit failed to follow established procedures during their review for the release of final drug products. Our review of your firm's records found out of specifications (OOS) and/or excursions that were not identified by your Quality Unit, and were signed as reviewed and released from your inventory into distribution. For example, but are not limited to:

A. **Routine** (b) (4) **Gowning Failures:** According to your firm's Quality Control Unit, who conducts all EM sampling at your firm, explained (b) (4) gowning EM is conducted (b) (4) (b) (4)

1. Several lots were released and distributed that were found to be out of specification for Gowning Failures by personnel involved in implantable hormonal pellet production. For example, but are not limited to:
   i. On 05/24/2017, your (b) (4) gowning sampling revealed a total of 7 CFUs identified as *Coagulase-negative Staphylococcus spp.* and *Micrococcus/Kocuria spp.* A deviation for this incident was initiated on 01/29/2018 (8 months after the

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incident).This employee continued implantable hormonal pellet production from 05/24/2017 – 01/31/2018. Corrective actions for this incident were not initiated until 02/14/2018 (approximately 9 months after the incident). Lots produced by this technician on 05/24/2017 were released by your Quality Unit.

ii. On 05/30/2017, your (b) (4) gowning sampling revealed a total of 6 CFUs identified as *Coagulase-negative Staphylococcus spp*. and *Micrococcus/Kocuria spp.* A deviation for this incident was initiated on 01/29/2018 (8 months after the incident).This employee continued implantable hormonal pellet production from 05/30/2017 – 01/31/2018. Corrective actions for this incident were not initiated until 02/14/2018 (approximately 9 months after the incident). Lots produced by this technician on 05/30/2017 were released by your Quality Unit.

iii. On 12/21/2017, your (b) (4) gowning sampling revealed a total of 3 CFUs identified as fungus. Your Quality Unit failed to review this report. As a result, this lot was dispensed and a deviation was not initiated documenting this incident prior to this inspection. This employee continued implantable hormonal pellet production from 12/21/2017- 01/31/2018. In addition, your firm failed to conduct appropriate cleaning in accordance with your firm's written procedures after mold/fungus is detected. Lots produced by this technician on 12/21/2017 were released by your Quality Unit.

B. **Batch Environmental Monitoring Failures:**

1. Several lots were released and distributed that were found to be out of specification for Fingertip Failures by personnel involved in implantable hormonal pellet production. For example, but are not limited to:

   i. On 09/06/2017, fingertip environmental sampling revealed 1 CFU and too numerous to count ("TNTC") CFUs. However, your report identifying the

organism(s) did not include results of the "TNTC" plate. The 1 CFU was identified as *Bacillus cereus*. This excursion was not identified by your Quality Unit prior to final batch release. As a result, this lot was dispensed and a deviation was not initiated documenting this incident prior to this FDA inspection. This employee continued implantable hormonal pellet production after 09/06/2017. In addition, your firm failed to conduct cleanings in accordance with your firm's written procedures after spore-forming organisms are detected.

At least (b) (4) units of Testosterone 200mg, lot #09062017TN3, were distributed.

C. **Non-Viable Air Sampling Failures:**

1. Several lots were released and distributed that were found to be out of specification for non-viable air sample and relative humidity. These OOSs were not identified by your Quality Unit prior to final batch release:
   i. On 08/03/2017, during the production of Testosterone 200mg, Lot #08032017TN1, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)) and an OOS for relative humidity. Your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units of this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.
   ii. On 08/22/2017, during the production of Testosterone 200mg, Lot #08222017TN3, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)) and an OOS for relative humidity. Your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.
2. Several lots were released and distributed that were found to be out of specification for non-viable air samples. These OOSs were not identified by your Quality Unit prior to final batch release:

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i. On 09/29/2017, during the production of Testosterone/Anastrozole 200 mg/20 mg Pellet, Lot #09292017TN1, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)). Your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.

ii. On 10/04/2017, during the production of Testosterone 200 mg Pellet, Lot #10042017TN2, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)). Your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.

iii. On 10/09/2017, during the production of Testosterone 100 mg Pellet, Lot #10092017TN1, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)) as an OOS. However, your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.

iv. On 10/09/2017, during the production of Testosterone 200 mg Pellet, Lot #10092017TN3, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)). However, your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.

v. On 10/11/2017, during the production of Testosterone 200 mg Pellet, Lot #10112017TN3, your Head of QA recorded a non-viable air sampling reading failure ((b) (4) acceptance limit is (b) (4)). However, your Quality Unit failed to review this batch record thoroughly. As a result, at least (b) (4) units from this lot were dispensed. In addition, your Quality Unit failed to initiate a deviation documenting this incident.

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OBSERVATION 2

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

Specifically,

A. During an interview with your firm's pharmacists that was conducting review and sign off on testing QC lab reports stated they did not know what they were reviewing. These documents included, but are not limited to: Certificate of (b) (4) Raw Material Certificate of Analysis, and Final Release Specifications.

B. During an interview with your firm's Head of Quality Assurance, who reviews environmental monitoring data, stated they sign to ensure the technician has filled the paper work correctly and could not remember if they verified the accuracy of the data recorded. In addition, your Head of QA signed this document as verified, without a technician's signature.

C. Environmental Monitoring is not always conducted on all employees engaged in production. However, these documents are signed as reviewed by your Quality Control Unit.

D. During our review of your firm's batch records, which are signed by a Pharmacist and your Quality Control Unit, we observed the following discrepancies:
   1. During the review of Testosterone 100mg, Lot #04172018TN3, your firm's QA Pellet Calculation worksheet documented (b) (4) product waste and your firm's batch record documents (b) (4) of waste; however, the units should been (b) (4) . These records were reviewed and approved by your Quality Unit and your Pharmacist.
   2. On 04/17/2018, during the production of Testosterone 100mg, Lot #04172018TN3, we observed the tool used in the Pellet Press during production was broken. However, our

batch record review, conducted on 04/25/2018, we noted your batch record did not document this incident took place during production. No deviation was not initiated.

3. During our interview of your firm's Pharmacist, who conducted the verification process of Testosterone 100mg, Lot #04172018TN3 during production, stated they did not check the calibration stickers on the equipment used during production. However, the batch record addresses all equipment calibration logs are to be reviewed in accordance with the firm's written procedures. Your Senior Director of Quality stated your firm does not have any Equipment Calibration Logs and the SOP and Batch Records need to be updated.

E. Your Head of Quality Assurance failed to appropriately read the gowning validation media plates on 04/16/2018. In addition, the (b) (4) plates were not sent for speciation identification. No deviation was initiated during our inspection.

OBSERVATION 3

The flow of components, drug product containers, closures and drug products though the building is not designed to prevent contamination.

Specifically,

A. On 4/19/2018, during the production of Testosterone 12.5mg (lot #04192018TN1, exp. 10/16/2018), we observed the following deficiencies:
   1. Production personnel use a non-cleanroom calculator in the ISO 7 cleanroom. Your firm's cleaning procedures for the introduction of this equipment into the non-dedicated ISO-7 areas are deficient and do not ensure cross-contamination does not occur. In addition, this calculator is not easily cleanable and your environmental monitoring sampling plan does not include taking samples of this calculator.

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2. During your firm's cleaning of the ISO 7 area, we observed the enclosed analytical balance (in the ISO 7 cleanroom) used to measure Testosterone powder during production was not adequately cleaned to prevent cross-contamination.

B. On 4/17/18 and 04/19/2018, we observed the movement of personnel and materials, utilized for implantable pellet hormonal production, move from a dirty area to a cleaner area without being disinfected. For example, but not limited to:
   1. A non-dedicated tool, which comes into direct contact with drug components, left the Pellet Packaging Room (ISO 7) to the Anteroom (ISO 8) and from the Anteroom (ISO 8) into the Pellet Room (ISO 7), was not disinfected. This tool was used in the production of Testosterone 100mg pellets, lot # 04172018TN3, exp. 10/14/18.
   1. A non-dedicated sieve, which comes into direct contact with drug components, was transferred from the Anteroom (ISO 8) into the Pellet Packaging Room (ISO 7), and not disinfected. This sieve was used in the production of Testosterone 12.5mg pellets, lot # 04192018TN1, exp. 10/16/18.

OBSERVATION 4

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

Specifically,

A. Cleanings are conducted sporadically.
   1. Pharmacy staff is responsible for conducting cleanings of the Pellet Suite (ISO 7 and ISO 8 areas) and the Sterile Injectable Suite (ISO 5, ISO 7, and ISO 8 areas).
      i. For example, but not limited to, the 2017 cleaning records for your firm's Pellet Suite documents:

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a. (b) (4) cleanings did not occur 6 out of (b) (4) .
b. (b) (4) cleanings did not occur the (b) (4) .

ii. For example, but not limited to, the 2018 cleaning records for your firm's Sterile Injectable Suite (ISO 5, ISO 7 and ISO 8 areas) documents:
   a. (b) (4) cleanings did not occur 58 out of (b) (4) from 01/01/2018 – 03/31/2018.
   b. (b) (4) cleanings did not occur (b) (4) from 01/01/2018 – 03/31/2018.

iii. For example, but not limited to (b) (4) Cleanings ((b) (4) Cleaning) shall be performed (b) (4) . However, your cleaning records document (b) (4) cleanings were not performed (b) (4) in your Sterile Injectable Suite:

Date of Certification	Room	Classification
04/04/2017	(b) (4) LAFH	ISO-5
04/04/2017	Clean Room (New)	ISO-7
04/04/2017	Prep Room (New)	ISO-8
04/04/2017	Anteroom (New)	ISO-8
09/18/2017	(b) (4) LAFH	ISO-5
09/18/2017	Clean Room (New)	ISO-7
09/18/2017	Prep Room (New)	ISO-8
09/18/2017	Anteroom (New)	ISO-8

According to your firm's Senior Director of Quality Assurance, your firm intends to produce sterile injectable drug products for distribution.

B. A cleanroom dedicated vacuum cleaner, purchased on August 2016, was observed in use by the operator to vacuum the floors of the ISO 7 and ISO 8 Cleanroom areas where implantable pellets are produced. Your firm's Senior Director of QA stated no environmental sampling has been conducted on this vacuum. In addition, your firm failed to ensure this vacuum was:

2. appropriate for use with hazardous drug products;
3. cleaned per the manufacturer's recommendations to prevent microbial growth;
4. (b) (4) inspected.

C. We observed what appeared to be residual drug powdered fingerprints on the glass window located in the ISO 7 Pellet Packaging Room (approximately (b) (4) away from the pellet and blister machines) from 04/16-20/2018. Your firm continued to produce implantable hormonal pellets. For example, but are not limited to:

Lot number	Drug
04172018TN1	Testosterone 100mg
04172018TN3	Testosterone 100mg
04192018TN1	Testosterone 12.5mg
04202018TN1	Estradiol 25mg

D. On 4/16/18, your firm's Pharmacist in Charge (PIC) stated they initiated a batch of DHEA in the ISO 7 Pellet Package Room. However, this process was halted due to an OOS for humidity in the ISO 7 Pellet Package Room. During our review of your firm's cleaning records, we observed cleaning was not performed prior to the production of Testosterone 100mg, lot #4172018TN1 and lot #04172018TN3 on 04/17/18. Your firm's cleaning records documents the last cleaning performed prior to the production of these lots in the ISO 7 Pellet Packaging Room was on 04/13/2018.

OBSERVATION 5

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

Specifically,

A. Your firm's smoke studies and Room Certifications are deficient and does not support the maximum allowable number of personnel engaged in drug production at any given time. In addition, on 4/17/18, we observed three people in the ISO 8 Anteroom. Your firm's written procedures states (b) (4) .

B. Your firm failed to conduct cleaning validation studies, including but not limited to: disinfectant effectiveness studies to demonstrate that the disinfectants used to clean the equipment, walls, floors, ceilings, and work surfaces in the ISO 5, 7, and 8 areas can sufficiently reduce bioburden or cross-contamination.
   a. In addition, your firm uses (b) (4) as a sporicidal cleaning agent. However, your firm did not provide any supporting documentation justifying the use of this sporicidal with a (b) (4) contact time. The manufacturer's recommendation states this cleaning agent is to be used for (b) (4) to be an effective sporicidal cleaning agent.

C. In addition, your firm has not conducted any hold time studies to support a (b) (4) time lapse between the cleaning of equipment prior to production of your firm's implantable drug pellets.

D. Your firm's Senior Director of QA stated your firm uses (b) (4) during the cleaning of the (b) (4) pellet press used in the production of implantable pellets. However, during our review of your firm's cleaning records, we observed the COA that accompanies the (b) (4) was not sterile.

E. On 04/19/2018, prior to conducting implantable hormonal pellet production, we observed your pharmacy technician touching the outside of the glove with their ungloved hand, compromising the sterility of the glove prior to donning sterile gowning.

OBSERVATION 6

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

Specifically, your firm does not use (b) (4) or similar media plates during routine environmental monitoring.

In addition, the Certificate of Analysis for the (b) (4) plates purchased by your firm can detect *escherichia coli* or *salmonella typhimurioum* growth. However, your growth promotion tests are deficient in that they do not include *escherichia coli* or *salmonella typhimurioum* growth. In addition, your firm does not follow the established ATCC incubation recommendations to detect these organisms.

OBSERVATION 7

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, your firm has structural and equipment deficiencies in the classified areas which do not ensure clean air flow.

C. The HEPA filters are located adjacent (approximately (b) (4) apart) to the air return vents in the ceiling of the ISO 7 Pellet Production Room where implantable hormonal pellet production occurs.

D. Three (3) chairs located in the ISO 7 cleanrooms (pellet and package cleanroom) are not easily cleanable. We observed the chairs to have large tears (approximately 2"- 6" long and ½" – 1" wide) exposing the sponge/foam stuffing to the ISO 7 environment. These chairs are used by personnel during the production of implantable hormonal pellets produced at your firm.

E. We observed fluorescent light fixtures with covers in the ISO 7 package room that are not smooth and are not easily cleanable.

F. Excess caulking was observed in the ISO 7 cleanrooms (package and pellet) and the ante area (ISO 8). The caulking is not smooth and non-porous. For example, but are not limited to:
   1. On the ceilings;
   2. Around the wire for the pellet labeling machine;
   3. Around the capped water pipes of the ante area where a sink was removed.

G. A portable speaker, located in the ISO 7 package cleanroom, was observed to have what appeared to be residual drug powdered fingerprints.

H. Pharmacy staff is responsible for conducting cleanings of the (b) (4) For example, but not limited to, the 2017 - 2018 cleaning records for your firm's (b) (4) located in an unclassified area, documents:
   1. (b) (4), and (b) (4) cleanings should occur. However, the equipment (b) (4) Validation Log, where cleaning is documented, indicates:
      i. (b) (4) cleaning did not occur in 2017 or 2018
      ii. (b) (4) cleaning did not occur at least 21 times from 2/28/2017 to present
      iii. (b) (4) cleanings did not occur 13 times from 2/28/2017 to present (b) (4)
      iv. According to your firm's written procedure, SOP 4.032: "*Use and Maintenance of the* (b) (4) *Dyersburg, TN*", (b) (4) .

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According to your firm's Head of Quality Assurance, the air filters have not been replaced since November 2016.

OBSERVATION 8

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

A. During our review of your firm's batch records, we observed the following deficiencies. For example, but are not limited to:

1. The second verification signature was signed prior to the operator who performed the duties as outlined in the batch record for Testosterone 100mg, Lot #04172018TN1.
2. The technician(s), that performed the operations for Testosterone 100mg, Lot #04172018TN1 and Lot #04172018TN3, stated they signed the batch record for each operation, but the operation may have actually been performed by a different operator.
3. The start time and completion time was documented after the completion of Testosterone 100mg, Lot #04172018TN1.
4. Environmental Monitoring Records are to be performed during the production of (b) (4) (b) (4) produced at your firm. This operation is verified by a pharmacist on your firm's Batch Records. However, during our review of Personnel Monitoring (e.g. Finger Tip Testing) after DHEA, Lot #04172018TN2, a technician involved in the production of this batch was not fingertip tested by your Quality Assurance Assistant. This Batch was signed as verified by your pharmacist.
5. We observed sticky notes attached to your firm's batch record for DHEA 25mg, Lot #PV04182018TN1, to capture calculations performed.

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B. During an interview on 04/18/2018, two (2) of your firm's pharmacists independently stated they do not always perform the actual yields calculations during batch record review for drug products compounded at your firm.

C. During the production of pellets, samples of drug product are weighed to confirm the dose. For example:

1. Adjustments are made to the pellet press based on the weight of the tablets. However, your batch record does not document the weights taken by the technician prior to adjusting the pellet press. These weights are not verified by a second reviewer. In addition, the analytical balance does not have a print-out verifying weights taken. There is no print-out from the analytical balance verifying the weights documented on your firm's batch records.

2. (b) (4) Pellets are weighed at the end of Pellet Production. However, the weights recorded are not verified by a second reviewer at the time of performance. There is no print-out from the analytical balance verifying the weights documented on your firm's batch records.

D. On 4/19/2018, during the production of Testosterone 12.5mg (lot #04192018TN1 exp. 10/16/2018), we observed finished drug pellets stored on an uncovered weigh boat (located approximately (b) (4) from the Pellet Machine and Blister Packaging Machine in the ISO 7 area. These machines were being cleaned; exposing the finished product to your firm's cleaning agents.

OBSERVATION 9

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

Specifically,

A. Your firm's Quality Control Unit failed to ensure the Air Sampler, (EQ ID #(b) (4) was within calibration prior to use. During our review of your firm's records, we observed this Air Sampler to be out of calibration from approximately May – July 2017. Your firm conducts non-viable air samples during (b) (4) of implantable hormonal pellets produced at your firm. This failure resulted in the release the following lots. For example, but are not limited to:

Lot number	Drug	Units Dispensed
06052017TN1	Progesterone 100mg	(b) (4)
06122017TN1	Testosterone 18mg	(b) (4)
06122017TN2	Testosterone 62.5mg	(b) (4)
06202017TN2	Testosterone 80mg	(b) (4)
07112017TN1	Testosterone 100mg	(b) (4)

B. Your firm failed to follow your written procedure, SOP 6.090: *"Pellet Production Dyersburg, TN"*, section 8.11 which states (b) (4) . However, during our batch record review, (b) (4) calibrations are not performed or documented.

OBSERVATION 10

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Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm received five (5) complaints in 2017 and four (4) complaints to date in 2018, related to infection, extrusions, and potency concerns. However, 8 of the 9 complaints were closed and signed by your Senior Director of Quality Assurance on 04/17/2018, during this FDA inspection. The complaint records are deficient in that they do not contain documentation an investigation was initiated, batch records were reviewed, or analytical data was reviewed prior to their closure.

Your firm's written procedure, SOP 9.290: *"Drug Product Complaint"*, section 8.6 states (b) (4) (b) (4) . Your complaint records do not contain any such memos. Complaints were observed to be opened greater than 140 days prior to closure.

OBSERVATION 11

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, during our record review, we observed multiple out-of-specification failures. Your firm failed to open an investigation in accordance with your firm's established written procedures. However, your firm's Senior Director of Quality Assurance stated many of these failures are recorded in Deviations. During our review of your firm's deviations, we found the documentation to be deficient. For example, but are not limited to: root causes are not assessed; corrective action and preventative actions are not documented; there is a failure to extend the investigation (deviation) to other batches; and lot numbers are not recorded.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Angie C. Andrews, Director of Operations	
FIRM NAME Wells Pharmacy Network, LLC	STREET ADDRESS 450 US Highway 51 Byp N
CITY, STATE, ZIP CODE, COUNTRY Dyersburg, TN 38024-3655	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 12

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. During the inspection, we observed an uncontrolled, non-validated excel spreadsheet used to perform calculations that are attached to each Pellet Batch Record. This spreadsheet is not maintained through document control and there is no protection from data manipulation, overwriting, erasing of data, or audit trails. In addition, this spreadsheet was found on the (b) (4) Drive of your firm's Quality Assurance Assistant and Head of Quality Assurance. Your firm's Head of QA stated she had multiple versions of this spreadsheet. Your QA Assistant stated, the excel spreadsheets are not uniquely saved after performing calculations for individual batches and demonstrated the previous excel version may be overwritten.

B. Your firm failed to ensure the Software, (b) (4) , for your (b) (4) Pellet Press, with (b) (4) during the pellet press production is not altered in a manner that will affect final drug product. According to your firm's Senior Director of Quality Assurance, this software does not have audit controls and is not password protected. However, two pharmacy technicians involved in pellet production explained they can override the (b) (4) to make adjustments during the pellet production (e.g. (b) (4) These adjustments are not recorded on your firm's batch records. Your firm uses the pellet press for the following products, but are not limited to:

- Progesterone
- Testosterone

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE June P Page, Investigator Pallavi K Lele, FDA Center Employee or Employee of Other Federal Agencies	X June P Page Investigator Signed By: 2000405709 Date Signed: 04-27-2018 13:31:48	DATE ISSUED 4/27/2018

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- Testosterone (b) (4)
- Testosterone/Anastrozole
- PLT Estradiol
- PLT Testosterone
- Estradiol
- Testosterone Cholesterol
- ESTRADIOL/ESTRIOL
- PLT BIEST (50/50)
- PLT DHEA

OBSERVATION 13

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm uses a (b) (4) Mixer, according to your firm's Director of Operations, is set at (b) (4) for (b) (4) . However, your Senior Director of Quality Assurance stated your firm has not conducted content uniformity testing to validate the mixing and time parameters specified on your firm's batch record.

***DATES OF INSPECTION**

4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed), 4/19/2018(Thu), 4/20/2018(Fri), 4/23/2018(Mon), 4/24/2018(Tue), 4/25/2018(Wed), 4/26/2018(Thu), 4/27/2018(Fri)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Angie C. Andrews, Director of Operations

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network, LLC	450 US Highway 51 Byp N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dyersburg, TN 38024-3655	Outsourcing Facility

X Pallavi K Lele
FDA Center Employee or Employee of Other Federal Agencies
Signed By: Pallavi K. Lele -S
Date Signed: 04-27-2018 13:32:16

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EMPLOYEE(S) SIGNATURE

June P Page, Investigator
Pallavi K Lele, FDA Center Employee or Employee of Other Federal Agencies

X June P Page
Investigator
Signed By: 2000405709
Date Signed: 04-27-2018 13:31:48

DATE ISSUED
4/27/2018