

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

DISTRICT ADDRESS AND PHONE NUMBER  404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov		DATE(S) OF INSPECTION  12/1/2020-1/28/2021*
		FEI NUMBER  3011761321
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  Angie C. Andrews, Director of Operations		
FIRM NAME  Wells Pharmacy, Inc	STREET ADDRESS  450 Us Highway 51 Byp N	
CITY, STATE, ZIP CODE, COUNTRY  Dyersburg, TN 38024-3655	TYPE ESTABLISHMENT INSPECTED  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**

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,

- A. Testosterone 100mg (Lot# 03182020TN<sup>(b)(4)</sup>) implantable hormonal pellets intended to be sterile, failed sterility testing for *Chaetomium globosum* (fungus) after (b) (4) sterilization from your third-party contract testing laboratory. Your quality unit noted an 81% recovery of *Chaetomium globosum* over the last 30 months, with an increasing frequency over the last 12 months. In addition, a third-party janitorial company concluded, “the HVAC system including the (b) (4) the air returns, walls, ceilings, and floors of the suite were all contaminated with mold.” Your firm’s quality unit failed to conduct a thorough investigation to address the source of this contamination. For example, but not limited to, your firm’s Vice President of Quality Assurance stated on 09/02/2020, a third-party contractor performed cleanings to eradicate your firm’s fungus/mold concerns. However, *Chaetomium globosum* was recovered at your facility on 10/07/2020.

According to your firm’s investigation report, provided by your firm’s Vice President of Quality Assurance, various fungus species have been recovered on several occasions between 2018-2020. For example, but not limited to:

Sample Site/Description	Lot#	ID (Fungus)	CFUs
A2: Air Sample -Pellet Press	05242018TN <sup>(b)(4)</sup>	<i>Penicillium camemberti</i>	1
A9: Air Sample - (b) (4) Mixer	N/A	<i>Fusarium spp., Penicillium chrysogenum</i>	2
A10: Air Sample -(b) (4) Mixer	N/A	<i>Chaetomium globosum</i>	1
A2: Air Sample -Pellet Press	05252018TN <sup>(b)(4)</sup>	<i>Penicillium camemberti</i>	1

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A2: Air Sample -Pellet Press	05292018TN	<sup>(b)(4)</sup> <i>Fusarium spp., Penicillium chrysogenum, Chaetomium globosum</i>	1
Right Fingertips	05292018TN	<sup>(b)(4)</sup> <i>Unidentifiable hyaline fungus, Fusarium spp., Penicillium chrysogenum,</i>	3
A2: Air Sample -Pellet Press	05312018TN	<sup>(b)(4)</sup> <i>Scopulariopsis spp; Chaetomium globosum</i>	2
A7: Air Sample <sup>(b)(4)</sup> Hood	05312018TN	<sup>(b)(4)</sup> <i>Chaetomium spp.; Penicillium spp.</i>	2
A5: Air Sample – Supply Rack	N/A	<i>Penicillium spp.; Fusarium proliferatum</i>	2
A1: Air Sample – Blister Pack Machine			
A4: Air Sample – Pellet Press	N/A	<i>Penicillium chrysogenum; Fusarium proliferatum</i>	2
A12: Air Sample – Pellet Packaging Suite Entrance	N/A	<i>Unidentifiable hyaline fungus</i>	1
A15: Air Sample – Bench	N/A	<i>Chaetomium spp.</i>	1
<sup>(b)(4)</sup> Gowning- 06/13/2018	N/A	<i>Non-sporulating hyaline fungus</i>	1
Left Fingertips	05152019TN	<sup>(b)(4)</sup> <i>Rhodotorula mucilaginosa</i>	1
Right Fingertips	05232019TN	<sup>(b)(4)</sup> <i>Pedobacter quisquiliarum</i>	1
Left Fingertips	06112019TN	<sup>(b)(4)</sup> <i>Chaetomium globosum</i>	1
Right Fingertips	06132019TN	<sup>(b)(4)</sup> <i>Chaetomium globosum</i>	1
Gowning Qualification	N/A	<i>Cladosporium cladosporioides/herbarum</i>	3
A13: Air Sample – Supply Rack	N/A	<i>Cladosporium cladosporioides Complex</i>	1
Left shoulder	N/A	<i>Curvularia pseudobrachyspora</i>	1
Left forearm	N/A	<i>Cladosporium cladosporioides Complex</i>	1
S21: Surface Sample – Near Supply Rack	N/A	<i>Acrodontium spp.</i>	1
Left Fingertips	07172019TN	<sup>(b)(4)</sup> <i>Chaetomium globosum</i>	1
Left fingertips	07172019TN	<i>Chaetomium globosum</i>	1
Right Fingertips	07222019TN	<i>Chetomium spp</i>	1
Right Fingertips	08082019TN	<i>Chaetomium globosum</i>	1
Left Fingertips	09052019TN	<i>Chaetomium globosum</i>	1
Right Fingertips	09122019TN	<i>Chaetomium globosum</i>	1
Left Fingertips	10102019TN	<i>Aspergillus sydowii</i>	1
Left Fingertips	10102019TN	<i>Chaetomium globosum</i>	1
A8: Air Sample – Pellet Press area	01082020TN	<i>Aureobasidium pullulans</i>	1
S8: Surface Sample – Pellet Press area	02192020TN	<i>Paecilomyces formosus</i>	1

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Sterility	03182020TN	(b) (4)	<i>Chaetomium globosum</i>	N/A
Left Fingertips	04302020TN		<i>Chaetomium globosum</i>	1
Left Fingertips	06172020TN		<i>Chaetomium globosum</i>	1
Left Fingertips	06182020TN		<i>Chaetomium globosum</i>	1
Air sample of pellet press	07142020TN		<i>Chaetomium globosum</i>	1
Surface sample of table	07/24/2020		<i>Chaetomium globosum</i>	1
Left Fingertips	07312020TN	(b) (4)	<i>Chaetomium globosum</i>	1
Left Fingertips	08072020TN		<i>Chaetomium globosum</i>	1
Surface Sample of the Pellet Press	08082020TN		<i>Chaetomium globosum</i>	1
Right Hand Fingertips	08082020TN		<i>Chaetomium globosum</i>	1
Left Hand	08082020TN		<i>Chaetomium globosum</i>	1
Surface sample of the (b) (4) (b) (4) mixer	n/a		<i>Chaetomium globosum</i>	1
Right Fingertips	10072020TN	(b) (4)	<i>Chaetomium globosum</i>	1

During our review of your firm's investigation report, which references the table listed above, we noted your Quality Unit failed to provide an accurate CFU count when compared to your firm's Micro ID reports. For example, but not limited to:

Sample Site/Description	Lot Number/EM Description	Organism Identified by your firm's 3-rd party contractor and CFU Count	Your Firm's Investigation Report Organism and CFU Count
Air Sample (A9)	(b) (4) Environmental Monitoring	<b>Total 5 CFUs:</b> • 3 CFU: <i>Penicillium chrysogenum</i> • 2CFU: <i>Fusarium proliferatum</i>	<b>2 CFU:</b> <i>Fusarium spp.</i> , <i>Penicillium chrysogenum</i>
Air Sample (A10)	(b) (4)	<b>Total 5 CFUs:</b>	<b>1 CFU:</b> <i>Chaetomium</i>

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	Environmental Monitoring	<ul style="list-style-type: none"> <li>• <u>3 CFU: Fusarium spp.</u></li> <li>• <u>2CFU: Chaetomium globsum</u></li> </ul>	<i>globsum</i>
Air Sample (A2)	05292018TN <sup>(b) (4)</sup>	<u>Total 7 CFUs:</u> <ul style="list-style-type: none"> <li>• <u>5 CFU: Fusarium spp.</u></li> <li>• <u>1 CFU: Penicillium chrysogenum</u></li> <li>• <u>1CFU: Chaetomium globsum</u></li> </ul>	<u>1 CFU: Fusarium spp.,</u> <u>Penicillium chrysogenum,</u> <u>Chaetomium globsum</u>
Personnel Monitoring (Right Fingertips)	05292018TN <sup>(b) (4)</sup>	<u>Total 9 CFUs:</u> <ul style="list-style-type: none"> <li>• <u>6 CFU: Penicillium chrysogenum</u></li> <li>• <u>2 CFU: Fusarium proliferatum</u></li> <li>• <u>1 CFU: Unidentifiable hyaline fungus</u></li> </ul>	<u>3 CFU: Unidentifiable</u> <u>hyaline fungus, Fusarium</u> <u>spp., Penicillium</u> <u>chrysogenum</u>
Air Sample (A7)	05312018TN <sup>(b) (4)</sup> & 05312018TN <sup>(b) (4)</sup>	<u>Total 6 CFUs:</u> <ul style="list-style-type: none"> <li>• <u>5 CFU: Chaetomium spp.</u></li> <li>• <u>1 CFU: Penicillium spp.</u></li> </ul>	<u>2 CFU: Chaetomium spp.,</u> <u>Penicillium spp.</u>
Air Sample (A5)	(b) (4) Environmental Monitoring	<u>Total 14 CFU:</u> <ul style="list-style-type: none"> <li>• <u>11 CFU: Penicillium spp.</u></li> <li>• <u>3 CFU: Fusarium proliferatum</u></li> </ul>	<u>2 CFU: Penicillium spp.;</u> <u>Fusarium proliferatum</u>
Air Sample (A1)	(b) (4) Environmental Monitoring	<u>Total 8 CFU:</u> <ul style="list-style-type: none"> <li>• <u>6 CFU: Penicillium spp.</u></li> <li>• <u>2 CFU: Fusarium proliferatum</u></li> </ul>	<u>2 CFU: Penicillium spp.;</u> <u>Fusarium proliferatum</u>
Air Sample (A4)	(b) (4) Environmental Monitoring	<u>Total 7 CFU:</u> <ul style="list-style-type: none"> <li>• <u>4 CFU: Penicillium chrysogenum.</u></li> <li>• <u>3 CFU: Fusarium proliferatum</u></li> </ul>	<u>2 CFU: Penicillium</u> <u>chrysogenum; Fusarium</u> <u>proliferatum</u>
Air Sample (A12)	(b) (4) Environmental Monitoring	<u>Total 15 CFU:</u> <ul style="list-style-type: none"> <li>• <u>15 CFU: Chaetomium spp.</u></li> </ul>	<u>1 CFU: Chaetomium spp</u>

Your firm continues to present with persistent fungus mold recoveries in your firm's production areas – please refer to OBSERVATION 1.B.

- B. Your firm's environmental and personnel monitoring data show a trend for mold and fungus recoveries in your firm's production areas. However, your firm has not conducted a thorough investigation, addressed the source of the contamination, or demonstrated the contamination is in a state of control. Your firm continues to produce implantable hormonal pellets.  
For example, but not limited to in 2020:

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(b) (4)	Fungus/Mold Microorganisms Identified	CFUs
(b) (4)	<i>Paecilomyces formosus</i>	1
	<i>Chaetomium globosum</i>	
	<i>Nigrospora sp.</i>	3
	<i>Pithomyces chartarum</i>	
	<i>Bipolaris cynodontis</i>	
	<i>Chaetomium globosum</i>	
	<i>Cladosporium cladosporioides</i>	7
	<i>Rhodotorula mucilaginosa</i>	
	<i>Chaetomium globosum</i>	2
	<i>Chaetomium globosum</i>	7
	<i>Acrodontium salmonicum</i>	
	<i>Aspergillus rubrobrunneus</i>	
	<i>Candida parapsilosis</i>	5
	<i>Cladosporium cladosporioides complex</i>	
	<i>Penicillium decumbens</i>	
	<i>Chaetomium globosum</i>	1

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C. Your firm's quality unit failed to conduct a thorough review of your firm's (b) (4) gowning results and associated released batch records:

**\*\*\*THIS IS A REPEAT OBSERVATION FROM FDA 483 issued in 2018 (Observation 1)\*\*\***

1. 10/10/2019 - (b) (4) Routine Personnel Monitoring: *Cladosporium cladosporioides* (mold) and *Bacillus spp.* were recovered on your firm's Pellet Assistant/Technician (left forearm), initials: (b) (4) during (b) (4) routine personnel monitoring for gowning on 10/10/2019. According to your firm's written procedure for personnel monitoring, routine personnel monitoring is conducted prior to exiting the cleanroom after compounding activities. Personnel monitoring samples were taken after your technician placed each pellet (b) (4) during packaging of Testosterone 50mg, Lot#10102019TN<sup>(b) (4)</sup>. A review of your firm's batch record for Lot# 10102019TN<sup>(b) (4)</sup> documents "n/a" for associated deviations related to Lot# 10102019TN<sup>(b) (4)</sup> by your firm's Quality Assurance Supervisor.

According to your firm's written procedures, "growth of fungus or mold automatically upgrades a sample to action level, (b) (4)" and "Lots associated with mold recovery will automatically result in a discard of the lot, after an investigation is completed to identify the root cause." This batch record was reviewed and approved by your firm's pharmacist and Senior Quality Assurance Manager and released for distribution.

10/10/2019 - Batch Routine Personnel Monitoring: *Chaetomium Globosum* (fungus) & *Aspergillus Sydowii* (fungus) was recovered on your firm's Pellet Assistant/Technician (gloved fingertips), initials: (b) (4) during batch routine personnel monitoring on 10/10/2019 during the production of Lot# 10102019TN<sup>(b) (4)</sup> which was produced prior to Lot# 10102019TN<sup>(b) (4)</sup>. Your Quality Unit rejected Lot# 10102019TN<sup>(b) (4)</sup>. However, your Quality Unit released Lot# 10102019TN<sup>(b) (4)</sup>.

01/20/2020 – Complaint received for Testosterone 50mg, Lot#10102019TN<sup>(b) (4)</sup> a complaint was received from the prescribing physician stating the Testosterone 50mg pellets received were "extremely yellow, hard and 'crusty'". Your firm's Quality Unit did not initiate an investigation

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(deviation) or conduct any testing on your firm's retain samples (e.g., sterility, hardness testing, dissolution). Please refer to **OBSERVATION 5**.

According to the distribution log, provided by your firm's Director of Operations, your firm released the following to the public:

Lot Number & Drug Product	Sum of Qty Dispensed
Lot # 10102019TN <sup>(b) (4)</sup>	
**(OS) Testosterone 50 mg Pellet	(b) (4)
**Testosterone (TN) 50 mg Pellet	
<b>Grand Total</b>	

2. 09/06/2019 - (b) (4) Routine Personnel Monitoring: *Curvularia pseudobrachyspora* (fungus) was recovered on your firm's production employee, initials: (b) (4) during (b) (4) routine personnel monitoring for gowning on 09/06/2019 after the production of Testosterone 12.5 mg Pellet (Lot# 09062019TN<sup>(b) (4)</sup>) and Testosterone (TN) 50 mg Pellet (Lot# 09062019TN<sup>(b) (4)</sup>). This report was received, reviewed, and signed by your Quality Unit on 10/08/2019.

In addition, batch record reviews for Testosterone 12.5 mg Pellet (Lot# 09062019TN<sup>(b) (4)</sup>) and Testosterone (TN) 50 mg Pellet (Lot# 09062019TN<sup>(b) (4)</sup>) were reviewed and released for distribution by your Quality Unit.

Furthermore, according to your firm's batch records for these lots, batch fingertip sampling was not performed on technician (b) (6), (b) (7)(C) who performed weighing and mixing of Testosterone for each

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lot. Your firm's written procedure requires fingertip sampling to be performed on each person involved in the compounding process.

According to the distribution log, provided by your firm's Director of Operations, your firm released the following to the public:

Lot Number & Drug Product	Sum of Qty Dispensed
09062019TN <sup>(b) (4)</sup>	
**(OS) Testosterone 12.5 mg Pellet	(b) (4)
**Testosterone (TN) 12.5 mg Pellet	
09062019TN <sup>(b) (4)</sup>	
**(OS) Testosterone 50 mg Pellet	
**Testosterone (TN) 50 mg Pellet	
<b>Grand Total</b>	

## **OBSERVATION 2**

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.

**\*\*\*THIS IS A REPEAT OBSERVATION FROM FDA 483 issued in 2018 (Observation 7)\*\*\***

Specifically, your firm has structural and equipment deficiencies in the classified areas which do not ensure clean air flow, including, but are not limited to:

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- A. In your firm's ISO 7-1 package room and ISO 7-2 pellet room where implantable hormonal pellets intended to be sterile are produced, we observed the following:
  - a. Gaps around the perimeter of your firm's ceiling HEPA filter screens and
  - b. Excess caulking located on the ceiling that is not smooth and not easily cleanable.
- B. In your firm's ISO 7-1 package room, the light fixtures are not smooth and are not easily cleanable.
- C. Your firm's (b) (4) Preventative Maintenance Report, dated 11/18/2020, performed by a third-party contractor, documents your facility has (b) (4) that have excessive rust damage. Your firm's Vice President of Quality Assurance provided a schematic of your facility's HVAC system and stated the (b) (4) referred to in this report are located above your firm's Pellet Suite.

Please refer to **OBSERVATION 4** for additional Quality Unit concerns.

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### **OBSERVATION 3**

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, on 12/01/2020, we observed obvious surface abrasions located on the faceplate of your firm's pellet press, EQ001, that come in direct contact with drug components during processing for implantable hormonal pellets intended to be sterile. Your firm's Vice President of Quality Assurance explained production operators would note equipment damages on your firm's batch record. However, your firm's written procedures for batch records do not address the documentation of equipment concerns. In addition, your firm's batch records do not have an allocated space for equipment concerns. Furthermore, your firm's written procedures for the preventative maintenance of the pellet press do not address the visual inspection of the pellet press for damages prior to production.

Your firm produced and released at least (b) (4) lots (approximately (b) (4) implantable sterile hormonal pellets) on EQ001 that are within expiry.

Please refer to **OBSERVATION 4** for additional Quality Unit concerns.

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

DISTRICT ADDRESS AND PHONE NUMBER  404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov		DATE(S) OF INSPECTION  12/1/2020-1/28/2021*
		FEI NUMBER  3011761321
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  Angie C. Andrews, Director of Operations		
FIRM NAME  Wells Pharmacy, Inc	STREET ADDRESS  450 Us Highway 51 Byp N	
CITY, STATE, ZIP CODE, COUNTRY  Dyersburg, TN 38024-3655	TYPE ESTABLISHMENT INSPECTED  Outsourcing Facility	

#### **OBSERVATION 4**

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.

**\*\*\*THIS IS A REPEAT OBSERVATION FROM FDA 483 issued in 2018 (Observation 2)\*\*\***

Specifically, during an interview with your firm's Quality Assurance Supervisor, who is onsite daily, is responsible for, but not limited to: review and release of your firm's batch records; routine monitoring reviews; and oversees your firm's environmental monitoring program, stated they do not make quality decisions due to lack of experience or authority. For example, but not limited to:

- A. On 12/07/2020, your firm's Quality Assurance Supervisor stated they acknowledged the gaps in your firm's ISO 7-2 Packaging Room and ISO 7-1 Pellet Room ceilings and stated these gaps may cause disruption in the quality of air. However, the Quality Assurance Supervisor does not review your firm's cleanroom certification reports and explained this review was conducted by the Quality Unit located in Ocala, Florida. Your firm's Director of Operations stated the Vice President of Quality Assurance, located in Ocala, Florida, visits their facility approximately (b) (4) and the Senior Quality Assurance Manager, also located in Ocala, Florida visits approximately (b) (4).
- B. On 12/01/2020, we observed obvious surface abrasions located on the faceplate of your firm's pellet press, EQ001, that comes in direct contact with drug components during processing for implantable hormonal pellets that are intended to be sterile. On 12/01/2020 and 12/07/2020, your firm's Quality Assurance Supervisor, who routinely reviews and authorizes the release of batch records, stated your firm did not have any assurances currently in place that would ensure the implantable hormonal pellets produced on EQ001 and released to the public were not free of metal inclusions (e.g., no metal detection devices). However, your firm's Quality Assurance Supervisor, stated they lack the authority to initiate an investigation (deviation) and defers to the Quality Unit located in Ocala, Florida for such determinations. On 12/10/2020, your firm's Director of Operations provided a dispensing report documenting at least (b) (4).

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lots (approximately (b) (4) implantable hormonal pellets) within expiry were distributed to the public. As of 12/10/2020, your firm's Vice President of Quality Assurance (located in Ocala, Florida) stated they were "still determining whether or not this constitutes a deviation due to a surface abrasion". Please refer to **OBSERVATION 3** for additional details.

### **OBSERVATION 5**

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

- A. Your firm received a complaint involving hospitalization and sepsis after a patient received Estradiol 6mg (Lot #05282019TN (b) (4)) Testosterone 37.5mg (Lot #04012019TN (b) (4)) and Testosterone 100mg (Lot #04222019TN (b) (4)). Your quality unit failed to conduct an investigation for this complaint. In addition, your 2019 Micro ID log report, provided by your firm's Vice President of Quality Assurance, documents your pellet production employees recovered *Staphylococcus epidermidis* and *Paenibacillus provencensis* during fingertip samplings on 04/22/2019 and 05/28/2019, respectively.

In addition, samples for personnel monitoring and environmental monitoring were taken at your facility on 04/22/2019 and 05/28/2019. The following microbiological organisms were identified:

Sample Date	ID	CFU
4/22/2019	<i>Staphylococcus epidermidis</i>	1
5/28/2019	<i>Micrococcus luteus</i>	27

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5/28/2019	<i>Staphylococcus epidermidis</i>	4
5/28/2019	<i>Dietzia cinnamea</i>	1
5/28/2019	<i>Staphylococcus hominis</i>	7
5/28/2019	<i>Micrococcus luteus</i>	5
5/28/2019	<i>Paenibacillus provencensis</i>	1
5/28/2019	<i>Paenibacillus lautus</i>	2
5/28/2019	<i>Coryneform bacillus</i>	1
5/28/2019	<i>Paenibacillus glucanolyticus</i>	1
5/28/2019	<i>Bacillus horneckiae</i>	3

Please refer to **OBSERVATION 8** for additional concerns.

B. Your firm's product complaint spreadsheets provided by your Vice President of Quality Assurance, documents at least 23% of the complaints received in 2019 and 45% of the complaints received in 2020 are related to the (b) (4), hardness, and/or broken pellets. Your firm has not conducted all specific testing appropriate for this dosage form.

Your firm continues to receive complaints related to hardness. However, your Vice President of Quality Assurance did not provide any supporting evidence that hardness testing was conducted for complaints received after 03/05/2019.

In addition, your firm's Vice President of Quality Assurance stated dissolution testing has not been performed as part of a complaint follow-up ensuring, for example, but not limited to:

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1. The pellet does not dissolve immediately (dose dumping);
2. The pellet remains integral;
3. A minimum amount of API is released by the pellet over a specified unit of time; and
4. The pellet releases API at a rate that is reproducible.

Please note failures addressed in **OBSERVATION 1.C.**

#### **OBSERVATION 6**

Individuals responsible for supervising the manufacture, processing, packing and holding of a drug product lack the training to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically, your SOP 9.300: *Training Program*, states GMP training shall be conducted for each employee (b) (4) based on date of previous GMP training. However, there are no assurances the following employees have completed your firm's (b) (4) and refresher CGMP training requirements.

Title	Date of Hire	Daily Duties and Responsibilities include but not limited to:
Vice President of Quality Assurance	04/2016	Ensures compliance with US FDCA, Section(s) 503A & 503B and all its related elements such as facilities, documentation, training, reports, and records (e.g. final review of all procedures, oversees all quality assurance, quality control, and regulatory duties).  <b>Please refer to OBSERVATIONS 1, 2, 3, 4, 5, 8 for quality concerns</b>
Vice President of Operations	07/2012	Oversees daily operations of Ocala, FL and Dyersburg, TN facilities (e.g. lab production; facility management; vendor management; evaluation, documentation, and

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	investigation of complaints).
	<b>Please refer to OBSERVATIONS 2, 5 &amp; 8 for quality concerns.</b>

#### **OBSERVATION 7**

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, your firm compound drug products that:

- (a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
- (b) are not identical or nearly identical to an approved drug but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- Testosterone 12.5 mg Pellets
- Testosterone 37.5 mg Pellets
- Testosterone 50 mg Pellets
- Testosterone 62.5 mg Pellets
- Testosterone 87.5 mg Pellets
- Testosterone 100 mg Pellets
- Progesterone 50 mg Pellets
- Progesterone 100 mg Pellets

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#### **OBSERVATION 8**

Your outsourcing facility has not submitted an adverse event report to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5).

Specifically, on 07/15/2019, your firm received an Adverse Event, ADR-TN 2019-001, for Estradiol 6 mg, Testosterone 37.5 mg, and Testosterone 100 mg pellets, for a patient that was hospitalized and tested positive for sepsis. However, this was not reported to FDA until 02/21/2020.

The Adverse Event Report was not reported to FDA within 15 calendar days after first receiving information about the adverse event.

Please refer to **OBSERVATION 5** for additional details.

#### **\*DATES OF INSPECTION**

12/01/2020(Tue), 12/02/2020(Wed), 12/03/2020(Thu), 12/04/2020(Fri), 12/07/2020(Mon),  
12/08/2020(Tue), 12/09/2020(Wed), 12/10/2020(Thu), 12/11/2020(Fri), 12/14/2020(Mon),  
12/15/2020(Tue), 12/16/2020(Wed), 12/17/2020(Thu), 12/18/2020(Fri), 12/21/2020(Mon),  
12/22/2020(Tue), 12/23/2020(Wed), 12/24/2020(Thu), 12/25/2020(Fri), 12/28/2020(Mon),  
12/29/2020(Tue), 12/30/2020(Wed), 12/31/2020(Thu), 1/01/2021(Fri), 1/04/2021(Mon),  
1/05/2021(Tue), 1/06/2021(Wed), 1/07/2021(Thu), 1/08/2021(Fri), 1/11/2021(Mon), 1/12/2021(Tue),  
1/13/2021(Wed), 1/14/2021(Thu), 1/15/2021(Fri), 1/18/2021(Mon), 1/19/2021(Tue), 1/20/2021(Wed),  
1/21/2021(Thu), 1/22/2021(Fri), 1/25/2021(Mon), 1/26/2021(Tue), 1/27/2021(Wed), 1/28/2021(Thu)

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