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	4/6/2026-4/9/2026
	FEI NUMBER 3011761321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jesse D. Werfel, Director of Operations

FIRM NAME	STREET ADDRESS
Wells Pharmacy, Inc	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 I OBSERVED:
Production System

OBSERVATION 1

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A) Inadequate Cleaning Validation

Your cleaning validation (Disinfectant Efficacy Study) does not evaluate whether your current cleaning agents and procedures effectively remove hazardous drug products to prevent cross-contamination or product carryover.

The cleaning agent manufacturer study provided as evidence for hazardous drug removal is inadequate for the following reasons:

- It only evaluated Estradiol and Progesterone, not all hazardous drug products manufactured at your facility.
- It only tested (b) (4) (b) (4) surfaces, not other product contact materials such as the plastic components of your firm's metal detector.
- It is not representative of your current procedure. The study used (b) (4) passes with the cleaning agent, but your cleaning procedure does not require a (b) (4) pass.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Demario L Walls, Investigator X Demario L Walls Investigator Signed By: DEMARIO L. WALLS - S Date Signed: 04-09-2026 14:01:14	4/9/2026

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Your firm's pellet press and metal detector are used during the manufacturing process of all hazardous drug products such as Testosterone, Estradiol, and Progesterone. For example, your firm used the (b) (4) Tablet Press and (b) (4) Metal Detector during the production of Testosterone 50mg Cholesterol, Lot 02242026TN2, expiration date 02/11/2027, and Estradiol 6mg, Lot 11202025TN2, expiration date 11/20/2026. Both sterile finished drug products were approved and released for distribution.

B) Inadequate Process Validation

Your firm's process validation failed to establish scientifically justified batch pellet yield sizes for compounded products. For example, your firm has established the following pellet yield sizes without justification or rationale:

Drug Product	Pellet Yield Size
Estradiol 6mg	(b) (4)
Estradiol 10mg	
Testosterone 50mg Cholesterol	
Progesterone 50mg	

Reviewed production batch records demonstrate significant variability in pellet weights. For example, Estradiol 10mg, lot 10212025TN3, expiration date 10/21/2026, had a total of 203 out-of-specification (OOS) pellets for weight out of (b) (4) pellets inspected. This lot was approved and released for distribution. Estradiol 6mg, lot 11202025TN2, expiration date 11/20/2026, had a total of 58 OOS pellets for weight out of (b) (4) pellets inspected. This lot was also approved and released for distribution.

Despite these high rates of OOS pellets (43% and 28%, respectively), no

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investigation was performed to determine the root cause. Both lots were approved and released for distribution.

Laboratory Control System

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm has failed to establish hardness specifications to demonstrate that these drug products conform to appropriate quality standards. Your hardness analyses demonstrate wide ranges of intra-batch results. For example, such variability was observed in the following lots:

Drug Product	Lot	Hardness Test Results Low (kgF)	Hardness Test Results High (kgF)	Qty Made	Qty Distributed
Testosterone 50mg Cholesterol	02242026TN2	4.4	20.9	(b) (4)	
Testosterone/Anastrozole 100/4mg	08262025TN2	5.4	13.6		
Estradiol 10mg	10212025TN3	8.3	12.7		
Testosterone 100mg SA	01232026TN4	4.7	15.0		
Testosterone 200mg SA	01222026TN3	13.1	20.7		
Progesterone 100mg	04262024TN2	1.02	2.63		
Testosterone 200mg SA	03272024TN3	4.76	11.86		

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Progesterone 100mg, Lot 04262024TN2, expiration date, received a complaint of 7 broken pellets in one order. Testosterone 200mg SA, lot 03272024TN3, expiration date, received a complaint of 3 pellets crumbling to dust when handling.

Since January 2025, your firm has received 8 complaints about broken pellets out of 20 total consumer complaints. Each lot was approved and released for distribution.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."