DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	4/14/2025-4/25/2025*
	FEI NUMBER 3011761321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jesse D. Werfel, Dir. of Operarions Tennesse

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 WE OBSERVED:

OBSERVATION 1

Each batch of controlled-release dosage form drug product is not laboratory tested to determine conformance to the specifications for the rate of release for each active ingredient.

Specifically,
Your firm failed to conduct dissolution testing as part of your finished product specification requirements prior to batch release, and therefore is unable to ensure subdermal implant pellets do not dissolve immediately, remain integral (do not crumble or break into pieces), and release active pharmaceutical ingredients at a rate that is reproducible. Dissolution testing has not been performed for the following sterile drug products:

Estradiol 6 mg
Estradiol 10 mg
Estradiol 12.5 mg
Estradiol 15 mg
Estradiol 18 mg
Estradiol 20 mg

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Dogbeda F Mackenzie, Investigator
Sangeeta M Khurana, Investigator

X Dogbeda F Mackenzie Investigator Signed By: DOGBEDA F MACKENZIE -A Date Signed: 04-25-2025 10:06:50

DATE ISSUED
4/25/2025

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Estradiol 25 mg
Progesterone 100 mg
Progesterone 50 mg
Testosterone (Cholesterol) 200 mg
Testosterone (Cholesterol) 100 mg
Testosterone (Cholesterol) 87.5 mg
Testosterone (Cholesterol) 50 mg
Testosterone (Cholesterol) 37.5 mg
Testosterone (Cholesterol) 25 mg
Testosterone (Cholesterol) 12.5 mg
Testosterone (Cholesterol 2%) 200 mg
Testosterone SA 200 mg Qty: 992
Testosterone SA 100 mg
Testosterone SA 87.5 mg
Testosterone SA 82.5 mg

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dogbeda F Mackenzie, Investigator Sangeeta M Khurana, Investigator	X Dogbeda F Mackenzie Investigator Signed By: DOGBEDA F MACKENZIE Date Signed: 04-25-2025 12:08 ET	DATE ISSUED 4/25/2025

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Testosterone SA 62.5 mg
Testosterone SA 50 mg
Testosterone SA 37.5 mg
Testosterone SA 25 mg
Testosterone/Anastrozole 100/4 mg
Testosterone/Anastrozole 200/8 mg
Testosterone/Anastrozole 200/20 mg
Naltrexone 200 mg (Pellecome)
Naltrexone 200 mg (BRX)
Naltrexone 1.1 g

OBSERVATION 2
Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,
Your firm has not demonstrated that your pellet container closure systems protect your sterile drug products from contamination throughout the life of the drug. You performed a (b) (4) container closure integrity study in 2016; however, the assigned BUDs for most of your drug products is

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Dogbeda F Mackenzie, Investigator Sangeeta M Khurana, Investigator X Dogbeda F Mackenzie Investigator Signed By: DOGBEDA F MACKENZIE -S Date Signed: 04-25-2025 12:08:35	4/25/2025

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approximately 12 months, and you have not extended the container closure integrity study to 12 months.

OBSERVATION 3

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

Specifically,
Your firm produces implantable hormone pellets intended to be sterile that have extended-release rates. However, your Quality Unit has not established hardness specifications to demonstrate that these drug products conform to appropriate quality standards. Your hardness analyses demonstrate wide ranges of intra-batch hardness results. For example:

Drug Product	Lot #	Hardness Test Results Low (kgF)	Hardness Test Results High (kgF)
Testosterone/Anastrozole 100/4 mg	(b) (4)	3.63	15.04
Testosterone Chol 87.5 mg		2.58	5.23
Testosterone SA 87.5 mg		8.86	~~16.58~~(please double check - the scanned copy was fuzzy) DM 4/25/2025
Estradiol 12.5 mg		1.64	3.81
Testosterone SA 62.5 mg		4.17	12.67
Progesterone 50 mg		0.94	2.33
Testosterone SA 100 mg		7.10	17.08
Testosterone SA 25 mg		5.17	19.32

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X Dogbeda F Mackenzie Investigator Signed By: DOGBEDA F MACKENZIE Date Signed: 04-25-2025 10:08 ED

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Since March 2024, your firm has received five adverse event complaints about pellet extrusions and 13 reports of pellets breaking.

OBSERVATION 4

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

1. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your blister drug product labels:

   a) The statement "This is a compounded drug";

   b) The name, address, and phone number of the outsourcing facility;

   c) The dosage form and strength;

   d) The quantity or volume;

   e) The date that the drug was compounded;

   f) The storage and handling instructions;

   g) The National Drug Code number, if available;

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h) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only."

Examples of your drug product labels that do not contain this information, include but are not limited to:

- Estradiol 6 mg pellet
- Estradiol 10 mg pellet
- Estradiol 12.5 mg pellet
- Estradiol 15 mg pellet
- Estradiol 18 mg pellet
- Estradiol 20 mg pellet
- Estradiol 25 mg pellet
- Naltrexone 200 mg / Triamcinolone 2 mg pellet
- Naltrexone 200 mg / Triamcinolone 2 mg pellet (without cholesterol)
- Naltrexone 1.1 g pellet
- Progesterone 100 mg pellet
- Progesterone 50 mg pellet
- Testosterone 100 mg / Anastrazole 4 mg pellet
- Testosterone 200 mg / Anastrazole 20 mg pellet
- Testosterone 100 mg pellet
- Testosterone 100 mg pellet (without cholesterol)
- Testosterone 12.5 mg pellet
- Testosterone 200 mg pellet (2% cholesterol)
- Testosterone 200 mg pellet (4% cholesterol)

Testosterone 200 mg pellet (without cholesterol)

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Testosterone 25 mg pellet
Testosterone 25 mg pellet (without cholesterol)
Testosterone 37.5 mg pellet
Testosterone 37.5 mg pellet (without cholesterol)
Testosterone 50 mg pellet
Testosterone 50 mg pellet (without cholesterol)
Testosterone 62.5 mg pellet
Testosterone 87.5 mg pellet
Testosterone 87.5 mg pellet (without cholesterol)

***DATES OF INSPECTION**
4/14/2025(Mon), 4/15/2025(Tue), 4/16/2025(Wed), 4/17/2025(Thu), 4/18/2025(Fri), 4/21/2025(Mon), 4/22/2025(Tue), 4/23/2025(Wed), 4/24/2025(Thu), 4/25/2025(Fri)

X Sangeeta M Khurana
Investigator
Signed By: SANGEETA M. KHURANA -S
Date Signed: 04-25-2025 10:09:53

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dogbeda F Mackenzie, Investigator Sangeeta M Khurana, Investigator	X Dogbeda F Mackenzie Investigator Signed By: DOGBEDA F MACKENZIE -S Date Signed: 04-25-2025 10:08:30	DATE ISSUED 4/25/2025

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."