DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	12/5/2022-12/8/2022* FEI NUMBER 3013497126

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert R. Roberts, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Triad Rx, Inc	26258 Pollard Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Daphne, AL 36526-4250	Non-Sterile Drug Producer

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

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, there is no deactivating agent used to clean work surfaces, utensils and (b) (4) in between production of different hazardous drug products. Hazardous drug products produced include but are not limited to, BI-EST 50:50 (Estriol/Estradiol) in Moisturizing Lotion 5% (50mg/ml) Cream, BI-EST 50:50 (Estriol/ Estradiol)/Pregnenolone 1.5mg/60mg per ml Cream, and BI-EST 50:50 (Estriol/Estradiol)/Progest/Testo/7-K-DHEA/Pregnen 0.25mg/35mg/0.75mg/10mg/3mg per 0.5ml Cream.

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*DATES OF INSPECTION

12/05/2022(Mon), 12/06/2022(Tue), 12/08/2022(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Veronica Fuentes, Investigator X Veronica Fuentes Investigator Signed By: Veronica Fuentes -S Date Signed: 12-08-2022 12:04:42	12/8/2022

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."