DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	9/17/2020-9/24/2020* FEI NUMBER 3013118095

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Philip E. Altman, Supervising Pharmacist

FIRM NAME	STREET ADDRESS
Healthy Choice Compounding LLC	250 Clearbrook Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Elmsford, NY 10523-1305	Producer of non-sterile drug products

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 segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

(A) The capsule machine is not cleaned with a deactivating agent after each compounding preparation. On 9/21/2020, I observed the technician compounding DI-EST PROG TEST SR 2.5/50/0.5 MG CAPSULE (Lot # 09182020@38), ESTRADIOL DHEA SR 0.25/5 MG CAPSULE (Lot # 09212020@2), and DHEA MICRO SR ((b) (4) (CLEAR/VEGGIE) 2.5 MG CAPSULE (Lot # 09212020@15). The capsule machine was vacuumed to remove remnants of (b) (4) and only wiped cleaned with (b) (4) in between compounding preparations.

(B) Deactivating agent is not used to clean the non-dedicated equipment used in the preparation of non-hazardous and hazardous drug products.

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, (b) (4) water was used as an ingredient in non-sterile compounded drug products, such as NALTREXONE 4 MG/ML LIQUID (Lot # 06032020@68) for Rx # (b) (6). Your firm did not conduct microbial and/or chemical analysis to ensure the quality of (b) (4) water used in your compounded preparations is pharmaceutical grade.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mindy M Chou, Investigator	Mindy M Chou Investigator	9/24/2020

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OBSERVATION 3

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, the following lots of compounded drug preparations were found to be out of specification after the lots were dispensed. However, no recall of the dispensed prescriptions was initiated following the receipt of the lab results.

Compounded Drug Product	Lot #	Potency ((b) (4))
DI-EST SR 2.0 MG CAPSULE	09152017@21	Estriol 134%
NALTREXONE 4.5 MG CAPSULE	10222019@31	86.5%
ESTRIOL DHEA 0.5/6.25 MG/GM VAGINAL	10152019@40	Estriol 84.8%
ESTRADIOL (OLIVE OIL) 0.01% (0.1 MG/GM) VAGINAL	11262019@43	43.6%
HYDROXYCHLOROQUINE ZINC 200/10 MG CAPS	04082020@57	Zinc 82.0%

***DATES OF INSPECTION**
9/17/2020(Thu), 9/21/2020(Mon), 9/24/2020(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mindy M Chou, Investigator	X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 09-24-2020 12:13:41	9/24/2020

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."