DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417 Industry Information: www.fda.gov/oc/industry	12/12/2019 - 12/20/2019
	FEI NUMBER 3015728736

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Arkadiy E. Khaimov, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
ABC Pharmacy, Inc.	16311 Ventura Blvd, Ste 110
CITY, STATE AND ZIP CODE Encino, CA 91436-4307	TYPE OF ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

Observation # 1
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,
A. Progesterone SR 50mg Lot # 082416 was tested on 09/19/2016 by a third-party contract laboratory and the potency was found to be 84.6%. The product was released for dispensing on 08/24/2016.

B. The drug product, DILT/LIDO 2/5% ONT Lot # Di2Li5101819, was assigned a BUD of 11/18/2019. Your firm dispensed the product on 11/22/2019 (RX # (b) (6)), 11/22/2019 (RX # (b) (6)), and 12/03/2019 (RX # (b) (6)) which are beyond the BUD assigned to the product.

Observation # 2
Hazardous drugs were produced without providing adequate cleaning of utensils to prevent cross-contamination. Specifically,

Your firm is using a spatula with wooden handle to produce hazardous drug products within the hazardous negative pressure room. The wood handle has a hard to clean surface which can potentially harbor microbial growth.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Uttaniti Limchumroon -S Digitally signed by Uttaniti Limchumroon -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300199793, cn=Uttaniti Limchumroon -S Date: 2019.12.20 16:24:29 -08'00'	Uttaniti Limchumroon, Investigator	12/20/2019