DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
1431 Harbor Bay Parkway	9/4/2018-9/14/2018*			
Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	FEI NUMBER 3002946561			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED John T. Sorci, Pharmacist				
FIRM NAME	STREET ADDRESS			
White House Pharmacy Inc. dba San Jose 2453 Forest Ave Compounding Pharmacy				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
San Jose, CA 95128-1505 Producer of Non-Sterile Drug Produce				

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 beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

a) Specifically, your firm produced beta-lactam products^{(b)(4)}times on the same day and in the same room (Lab Room) as non-beta lactam products. Your firm produces beta-lactam products on a shared table within 2 feet distance of non-beta lactam products.

This table shows the date made, beta-lactam and quantity of non-beta lactam product produced.

	Date Mad	le	Beta-Lactam Produced in Lab Room	Number of Non- Beta Lactam Products Produced in the Lab Room on the Same Day	
	12/16/201	6	Amoxicillin/Clavulanate 50MG/12.5MG/ML	(b) (4)	
	1/3/2017		Amoxicillin 350 MG Suppository		
	5/18/2017	7	Amoxicillin 100 MG Chew		
	7/5/2017	6	Amoxicillin 100 MG Chew		
	REVERSE THIS PAGE	23,1284)	ovee(s)signature istin M Abaonza, Investigator	Kristin M Abaonza mediadi pur sine signed 09-14-20 X	barroza-S 18 16 06 27
FORM	FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE INSPECTIO	ONAL OBSERVATIONS	PAGE 1 of 5 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER						
1431 Harbor Bay Parkway Alameda, CA 94502-7070				9/4/2018-9/14/2018* FEI NUMBER		
(510) 337-6700 Fax: (510) 337-6702			3002946561			
1000000	NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
1	nn T. Sorci,	Pharmacist	OTDEET ADDDE00			
1000-100-1	FIRM NAME White House Pharmacy Inc. dba San Jose 2453 Forest Ave					
Con	Compounding Pharmacy					
			ent NSPECTED c of Non-Sterile Drug Products			
Juli			11044001	or non boorre brag recaused		
		Amoxicillin 500MG/ML		(b) (1)		
	7/11/2017	Suspension		(b) (4)		
		Amoxicillin 500MG/ML				
	8/4/2017	Suspension				
		Amoxicillin 500MG/ML				
	8/31/2017	Suspension		_		
	10/13/2017	Penicillamine 125 MG Caps				
	12/4/2017	Ceftazidime 500 MG Supposi		_		
	12/5/2017	Ceftazidime 500 MG Supposi				
	12/29/2017	Penicillamine 125 MG Caps				
	3/6/2018	Penicillamine 125 MG Caps				
	4/9/2018	Penicillamine 125 MG Caps		_		
	5/17/2018	Ceftazidime 500 MG Supposi	tory			
		Amoxicillin 40MG/ML				
	5/22/2010	Suspension/Amoxicillin				
	5/23/2018	42MG/ML Suspension				
	5/29/2018	Penicillamine 125 MG Caps	ıle	_		
		Ceftazidime 500 MG				
	7/5/2018	Suppository/Amoxicillin				
	7/8/2018	100MG/ML Suspension Penicillamine 125 MG Caps	10	_		
				_		
	8/6/2018 8/14/2018	Ceftazidime 500 MG Supposi		_		
		Penicillamine 125 MG Caps	1970			
	9/4/2018	Penicillamine 125 MG Caps	ıle			
	b) Your firr	n cleans work surfaces (in betwee	en products	s) in your Lab Room with (b) (4)		
(b) (4) which is not effective in deactivating beta-lactams.						
SEE	and the second s	PLOYEE(S)SIGNATURE ristin M Abaonza, Investiga	tor	9/14/2018		
(- 1 () - 1	THIS PAGE			Kristin M Abaonza		
and and a second se	Signed By Kristin M. Abaenza - S Date Signed 09-14-2018 16 08 27 X					
TODA	ETD & (02 /00/00)		PECTIONAL	DBSERVATIONS PAGE 2 of 5 PAGES		
FURM	[FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	LECTIONAL C	OBSERVATIONS PAGE 2 of 5 PAGES		

DISTRICT ADDRESS AND PHO	DEPARTMENT OF HEAL	TH AND HUMAN	SERVICES		
DISTRICT ADDRESS AND PHOL		G ADMINISTRATIO	N DATE(S) OF INSPECTION		
1431 Harbor Bay Parkway			9/4/2018-9/14/2018*		
Alameda, CA		-	FEI NUMBER		
) Fax: (510) 337-6702	53	3002946561		
(010)001 0101	5 Tux. (010) 557 0702				
NAME AND TITLE OF INDIVIDU	al to whom REPORT ISSUED	· ·			
FIRM NAME	r, Fliathacist	STREET ADDRESS			
	Pharmacy Inc. dba San Joso	100.00000000000000000000000000000000000	et Avo		
White House Pharmacy Inc. dba San Jose 2453 Forest Ave Compounding Pharmacy					
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT	INSPECTED		
San Jose, CA 95128-1505 Pro			Producer of Non-Sterile Drug Products		
OBSER You pro cleaning contami Specific (b) (4) pr 9/6/2018	ally, your firm produced ^{(b) (4)} prescriptions of Fentanyl Sorbitol Ba	sils and clean ptions of Hyd se (Veggie) 5	ing of personnel to prever rocodone Bitartrate 10 M 00 MCG Lollipops from	nt cross- G capsules and 10/31/2016-	
	egg(e) (0) MC(t Lollinons in voir)	Lab Room w	while other patient specific	C. C. Contraction and Contraction of the	
were be to ^{(b) (4)} d b) Your	eggie) 500 MCG Lollipops in your ing produced, on a shared table with lifferent products can be produced a firm cleans work surfaces with (b)	h limited spac at one time. (4)	e. Your pharmacy technic , and dirty equipme	e prescriptions cian stated up nt (used to	
were bei to ^{(b) (4)} d b) Your produce	ing produced, on a shared table with lifferent products can be produced a firm cleans work surfaces with (b) highly potent products) with (b) (4	h limited spac at one time. (4) 4)	e. Your pharmacy technic , and dirty equipme	e prescriptions cian stated up	
were bei to ^{(b) (4)} d b) Your	ing produced, on a shared table with lifferent products can be produced a firm cleans work surfaces with (b) highly potent products) with (b) (4	h limited spac at one time. (4) 4)	e. Your pharmacy technic , and dirty equipme	e prescriptions cian stated up nt (used to	
were ber to ^{(b) (4)} d b) Your produce (b) (4) OBSER You pro	ing produced, on a shared table with lifferent products can be produced a firm cleans work surfaces with (b) highly potent products) with (b) (4	h limited spac at one time. (4) 4) ag highly pote	e. Your pharmacy technic , and dirty equipment ant residues.	e prescriptions cian stated up nt (used to and ^{(b)(4)}	
were ber to ^{(b) (4)} d b) Your produce (b) (4) OBSER You pro	ing produced, on a shared table with lifferent products can be produced a firm cleans work surfaces with (b) highly potent products) with (b) (which is not effective in removin EVATION 3 duced hazardous drugs without pro	h limited spac at one time. (4) 4) ng highly pote viding adequa nination.	e. Your pharmacy technic , and dirty equipment ant residues.	e prescriptions cian stated up nt (used to and ^{(b)(4)}	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	DATE(S) OF INSPECTION 9/4/2018-9/14/2018* FEI NUMBER 3002946561					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
John T. Sorci, Pharmacist FIRM NAME	STREET ADDRESS					
White House Pharmacy Inc. dba San Jose 2453 Forest Ave Compounding Pharmacy						
city, state, zip code, country San Jose, CA 95128-1505	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products					
Specifically, you produce patient specific prescriptions from hormonal Active Pharmaceutical Ingredients (APIs), such as Testosterone and Progesterone in your Hazardous Room at the same time as other hazardous products. Between 6/1/2018 and 9/4/2018, your firm produced ^{(b) (4)} progesterone prescriptions. a) Your written procedure entitled, "Cleaning and Maintenance of the Non-Sterile Compounding Area" SOP Number: 3.050 states in Section 10.0, "Approved cleaning solutions are (b) (4) (b) (4) or (b) (4) . Approved decontaminating solution is (b) (4) ." The above listed cleaning and decontaminating solutions used to clean work surfaces and dirty equipment in your Hazardous Room and are not effective in deactivating hazardous drugs. OBSERVATION 4 You used a non-pharmaceutical grade component in the formulation of a drug product. On 8/23/2018, your firm produced						
 pharmaceutical grade component, namely food grade "(b) (4) " (Lot#(b) (4) Expiration Date: 8/8/2019) manufactured by (b) (4) a) You stated that your firm ran out of (b) (4) and purchased food grade (b) (4) from the 						
grocery store to produce the Progesterone 100 MG capsules.						
*DATES OF INSPECTION						
SEE REVERSE OF THIS PAGE	tator Materia Abaonza Signed By Kristin M. Abaonza - S Date Signed Dy Kristin M. Abaonza - S Date Signed Dy Kristin M. Abaonza - S Date Signed Dy Kristin M. Abaonza - S					
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INS	SPECTIONAL OBSERVATIONS PAGE 4 of 5 PAGES					

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE 1431 Harbor Ba	NUMBER		DATE(S) OF INSPECTION 9/4/2018-9/14/2018*		
Alameda, CA 94	1502-7070	FEI NUMBER 3002946561			
(510)337-6700	Fax: (510) 337-6702		5002540301		
NAME AND TITLE OF INDIVIDUAL 1			2		
John T. Sorci,	Pharmacist	STREET ADDRESS			
108900000000000	armacy Inc. dba San Jose armacy	2453 Fore	est Ave		
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 9	NTRY TYPE ESTABLISHMENT INSPECTED			Products	
San Oose, CA S	5128-1505	rioducer	or Non-Scerrie Drug i	Toducts	
9/12/2018(Wed),	9/05/2018(Wed), 9/06/2018(Thu), 9/14/2018(Fri)	5/0//2018(1	(11), 9/10/2010(Moli), 9/11	/2018(1uc),	
a construction of the construction of the	EMPLOYEE(S)SIGNATURE Kristin M Abaonza, Investiga	itor	Kristin M Abaonza Imrestigato Babasi Date Signed 19-14-2016 16 08 27	DATE ISSUED 9/14/2018	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL O	BSERVATIONS	PAGE 5 of 5 PAGES	