		TH AND HUMAN SERVICE G ADMINISTRATION	ES	
DISTRICT ADDRESS AND PHON	ONE NUMBER		DATE(S) OF INSPECTION	
19701 Fairchi			11/8/2018-11/29/2018*	
Irvine, CA 92			3014549940	
(949)608-2900	Fax: (949) 608-4417	301131	,,,,,	
NAME AND TITLE OF INDIVIDUA	100 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Andrew C. Hoo	genson, Vice President Pharma	73		
231310310310	Inc. DBA Premier Pharmacy	STREET ADDRESS 410 Cloverleaf	Or	
Services				
CITY, STATE, ZIP CODE, COUN		TYPE ESTABUSHMENT INSPECTED		
Baldwin Park,	CA 91706-6511	Producer of Ste	rile Drug Produ	cts
observations, and do observation, or have action with the FDA	observations made by the FDA representative(s not represent a final Agency determination reg implemented, or plan to implement, corrective representative(s) during the inspection or submitact FDA at the phone number and address abo	arding your compliance. If y action in response to an obs it this information to FDA a	ou have an objection re ervation, you may discu-	garding an ss the objection or
DURING AN INSPEC	CTION OF YOUR FIRM I OBSERVED:			
and the second of the second o	eta-lactam drugs without providing	g adequate cleaning o	f work surfaces to	prevent cross-
contamination.				
		,		
Specifically,				
lactam drug prod There are (b) (4) There is no assur	ontaining penicillin are produced in the ucts; only a cleaning utilizing Sterile (ISO Class 5 hoods within the ISO Class ance that the cleaning process used with n-penicillin beta-lactam drug products.	o) (4) its 7 buffer room used thin the hoods prevents	s performed betwee by the firm to produ	n batches. ice sterile drugs.
500mg/100mL N Potassium, 3MU/ utilizing ^{(b) (4)}	[nycin HCl 850mg, Rx# n the production of the	(b) (6) followed se drug products, on	d by Penicillin G ly a cleaning
4				
		*		
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
SEE REVERSE OF THIS PAGE	Joey V Quitania, Investigat	or	Jony V Outrianto Investigator Bigned By: Jony V. Outranto - 8 Date Signed: 11-20-2018 10-10:25	11/29/2018
FORM FDA 483 (89/08)	BREVIOUS EDITION ORSOLETE IN	SPECTIONAL ORSERVATI	ONS	PAGE 1 of 2 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild 11/8/2018-11/29/2018* Irvine, CA 92612-2445 3014549940 (949)608-2900 Fax: (949)608-4417 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Andrew C. Hogenson, Vice President Pharmacy Operations STREET ADDRESS Good Health, Inc. DBA Premier Pharmacy 410 Cloverleaf Dr Services CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Baldwin Park, CA 91706-6511 Producer of Sterile Drug Products

OBSERVATION 2

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

Actionable microbial contamination was discovered inside the ISO Class 5 aseptic processing environment; however no evaluation of product impact was made.

For example, on 11/30/2016, an environmental monitoring sample collected from ISO Class 5 work surface, Hood# 67437, during cleanroom certification resulted in an actionable excursion of (b) (4) colony forming units. There were no documented corrective actions performed. In addition, there were no evaluations conducted for products made on or before 11/30/16 to include: Cefepime 1gm/50mL NS, Rx# (b) (6) (b) (4)

, Rx# (b) (6) ; Vanco 1gm/250mL, Rx# (b) (6)

*DATES OF INSPECTION

11/08/2018(Thu), 11/09/2018(Fri), 11/13/2018(Tue), 11/14/2018(Wed), 11/15/2018(Thu), 11/16/2018(Fri), 11/29/2018(Thu)

OFF DEVEDOR	EMPLOYEE(S) SIGNATURE	1	11/29/2018
SEE REVERSE OF THIS PAGE		Joey V Outlania Investigator Signed By: Josy V Outlania -S Date Signed: 11-29-2018 10:40.25	11/29/2018

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 2 PAGES