DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	11/8/2018-11/29/2018* FEI NUMBER 3014549940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew C. Hogenson, Vice President Pharmacy Operations

FIRM NAME	STREET ADDRESS
Good Health, Inc. DBA Premier Pharmacy Services	410 Cloverleaf Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Baldwin Park, CA 91706-6511	Producer of 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 beta-lactam drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically,

Drug products containing penicillin are produced in the same ISO Class 5 environment as non-penicillin beta-lactam drug products; only a cleaning utilizing Sterile (b) (4) is performed between batches. There are (b) (4) ISO Class 5 hoods within the ISO Class 7 buffer room used by the firm to produce sterile drugs. There is no assurance that the cleaning process used within the hoods prevents cross-contamination between penicillin and non-penicillin beta-lactam drug products.

For example, on 11/09/18, I observed the production the following drug products in Hood# E28777: Ertapenem 500mg/100mL NS, Rx# (b) (6) followed by Vancomycin HCl 850mg, Rx# (b) (6) followed by Penicillin G Potassium, 3MU/D5W 50mL, Rx# (b) (6). Between the production of these drug products, only a cleaning utilizing (b) (4) is performed. There is no cleaning agent used between products to effectively breakdown penicillin activity or the beta-lactam ring.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joey V Quitania, Investigator	X Joey V Quitania Investigator Signed By: Joey V. Quitania -S Date Signed: 11-29-2018 10:40:25	11/29/2018

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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)

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