DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/18/2016-7/28/2016* FEI NUMBER 3011319445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ponswamy Rajalingam , President & Owner

FIRM NAME	STREET ADDRESS
Hybrid Pharma LLC	1015 W Newport Center Dr Ste 106A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Deerfield Beach, FL 33442-7707	Outsourcing Facility

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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

a. A review of media fills conducted between 10/2015 and 04/2016 revealed that the media fills were not representative of actual production processes in that the media fills failed to simulate a lot with the maximum number of vials. The maximum vials observed in the media fill were (b)(4) vials. Your firm has filled the following:
   i. Cyanocobalamin 1000mcg/mL, lot #01PJ13: (b)(4) vials
   ii. Cyanocobalamin 1000mcg/mL, lot #03PM01: (b)(4) vials
   iii. Methylcobalamin 1mg/mL, lot #05PM12: (b)(4) vials
   iv. Methylcobalamin 1mg/mL, lot #03PM15: (b)(4) vials and (b)(4) vials

b. Your firm has not validated your (b)(4) Your firm uses a (b)(4) (b)(4) for the depyrogenation of glassware and amber vials (b)(4) used in the production of sterile injectable drug products.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

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Specifically,

a. We observed a reddish, yellowish-like discoloration on the HEPA filter inside of the ISO 5 hood. We also observed yellowish-like discoloration on the (b) (4) filter located to the left of the ISO 5 Hood and yellowish-like discoloration on the HEPA filter located to the right of the ISO 5 Hood. Your firm has not conducted any investigations into the discoloration of HEPAs (b) (4) prior to the current FDA inspection.

b. Your firm has not conducted disinfectant effectiveness studies to demonstrate that the disinfectants used to clean the walls, floors, ceilings, and work surfaces in the ISO 5, 7, and 8 areas can sufficiently reduce bioburden. Your firm uses the following cleaning solutions:
   i. Sterile (b) (4)
   ii. Non-Sterile (b) (4)
   iii. Non-Sterile (b) (4)
   iv. Non-Sterile (b) (4)
   v. Non-Sterile (b) (4)
   vi. Non-Sterile (b) (4)

c. Your cleanroom design is deficient in that:

   i. A black residue was observed after wiping the non-easily cleanable gasket-like surface of the ISO 5 Hood (b) (4) walls using a sterile lint free white wiper sprayed with sterile (b) (4). Furthermore, the sterile lint free white wipers are stored open on a metal cart

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that contains a white-like substance build-up.

ii. There is an approximately ½" gap around the perimeter of the door separating the ISO 8 Preparation Room from the ISO 7 Ante Room.

iii. Low wall vents from ISO 7 Buffer Room, ISO 7 Ante Room and ISO 8 Preparation Room open into general pharmacy area and are blocked by a bookshelf or desk. Furthermore, you stated (b)(4) fans have been placed in front of the vents in the general pharmacy area to prevent the accumulation of dust from blowing back into the ISO 7 Areas.

iv. Gray duct tape is being used around all (b)(4) of the ceiling tiles, 2 light fixtures and (b)(4) HEPA filters in the ISO 8 Preparation room. The owner stated the tape was applied over the caulking because tiles were still observed moving.

d. A reusable mop handle stored in the ISO 8 Preparation Room was moved into the ISO 7 Ante Room and ISO 7 Buffer Room without first being sanitized. Your procedure posted on the wall prior to entering the ISO 7 Ante Room states (b)(4) (b)(4)

OBSERVATION 3

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically, on 7/21/16, we observed the following:

a. Your operator's gowning touches the floor when donning non-sterile coveralls. We observed the upper arm of the non-sterile coveralls were inside of the ISO 5 zone during cleaning of the ISO 5 Hood.

b. Your operator donning the same gloves throughout the entire (b) (4) cleaning process for the ISO 5 Hood, ISO 7 Buffer Room counters, and ISO 7 Buffer Room floors. The operator's gloves came in contact with the flooring of the ISO 7 Buffer Room. The gloves were not changed or sanitized prior to cleaning the contact surface of the ISO 7 Ante Room workbench, ISO 7 Ante Room floors, ISO 8 Preparation Room counters and ISO 8 Preparation Room floors. Furthermore, all surfaces are not thoroughly wiped during the (b) (4) clean.

OBSERVATION 4

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically, your firm does not have validated methods to perform potency testing of sterile injectable products produced at your facility.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a. Your firm does not perform continuous pressure monitoring to ensure a cascading pressure differential is maintained throughout the cleanroom during production of sterile injectable products. Differential pressure readings are (b) (4) the magnehelic gauges (b) (4) There is no alarm system to notify the operator if a pressure excursion has occurred.

b. Your firm does not perform viable and non-viable environmental monitoring each day that sterile drug products are produced. For example, your firm compounded the following:

i. ALPHA LIPOIC ACID 50MG/ML Lot # 07PJ15B
ii. FOLIC ACID 10MG/ML lot# 07PJ05E
iii. PHOSPHATIDYL CHOLINE SODIUM DEOXY CHOLATE INJECTION 30mL Lot# 07PJ15
iv. ASCORBIC ACID 500mg/ml Lot # 03PM03B
v. B COM-50 Lot # 05PM09D
vi. GLUTATHIONE 200mg/ml Lot # 05PM16B
vii. NANDROLONE DECAN 200mg Lot# 07PJ13B

c. Your firm does not perform gloved finger-tip testing and personnel gown testing each day drugs purporting to be sterile are produced. For example, your firm compounded the following:

i. ALPHA LIPOIC ACID 50MG/ML Lot # 07PJ15B
ii. FOLIC ACID 10MG/ML lot# 07PJ05E
iii. PHOSPHATIDYL CHOLINE SODIUM DEOXY CHOLATE INJECTION 30mL Lot# 07PJ15
iv. ASCORBIC ACID 500mg/ml Lot # 03PM03B
v. B COM-50 Lot # 05PM09D
vi. GLUTATHIONE 200mg/ml Lot # 05PM16B
vii. NANDROLONE DECAN 200mg Lot# 07PJ13B

OBSERVATION 6
There is no written testing program designed to assess the stability characteristics of drug products.

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Specifically, your firm has not established a written stability program to assign beyond-use-dates greater than 60 days to your sterile injectable products.

OBSERVATION 7

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, your procedure for handling complaints and recalls is deficient in that it does not include:

b. Criteria for determination of whether the complaint represents an unexpected adverse event or a serious adverse event which requires reporting to the FDA.

c. Provisions to review the possible failure of the drug product to meet its specification.

d. Determination to conduct an investigation and extend to related drug if necessary.

OBSERVATION 8

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm utilizes the (b) (4) to perform in-house endotoxin testing. Per the manufacturer's instructions for use the (b) (4) should be calibrated (b) (4). Your records indicate the last calibration was (b) (4).

OBSERVATION 9

The labels of your outsourcing facility's drug products are deficient.

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The labels of your outsourcing facility's drug products does not include information required by sections 503B(a)(10)(A) & (B).

Specifically, the following information is not found on your drug product labeling:

- The statements, "This is a compounded drug," and "Not for resale;
- National drug code number;
- Storage and handling instructions;

Examples of drug products that do not contain this information:

- ALPHA LIPOIC ACID 50MG/ML
- FOLIC ACID 10MG/ML

In addition, the following information is not found on your drug product container labels:

- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug products that do not contain this information:

- THIAMINE VITAMIN B1 INJECTION 30mL
- PHOSPHATIDYL CHOLINE SODIUM DEOXY CHOLATE INJECTION 30mL

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7/18/2016(Mon),7/20/2016(Wed),7/21/2016(Thu),7/22/2016(Fri),7/25/2016(Mon),7/26/2016(Tue),7/28/2016(Thu)

7/28/2016

X Stephanie D Crockett

Stephanie D Crockett
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