DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, New York 11433 718-340-7000 Industry Information: www.fda.gov/oc/industry	4/22, 23, 24, 27 & 5/06/15
	FEI NUMBER 3005734706

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Stephen S. Laddy, CEO

FIRM NAME	STREET ADDRESS
Master Pharm, LLC	115-02 Liberty Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Richmond Hill, New York 11419	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) (WE) OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

a). Smoke studies were not performed under dynamic conditions to verify that operators, processing equipment or activities of the ISO 5 non-hazardous clean room (aka Clean Room (b)) do not alter or impede the unidirectionality of air from the HEPA filters to the ISO 5 processing stations where drug products are aseptically processed. Similarly, smoke studies were not performed under dynamic conditions for the ISO 7 hazardous clean room (aka Clean Room (b)), nor the ISO 5 (b) (4) and the ISO 5 (b) (4) within that room.

b). During the processing of Morphine/Bupivacaine/Clonidine Intrathecal syringe lot 04-22-2015:53@5 on 4/22/15 in Clean Room (b), I observed the following: On the ISO 5 work station where open containers of sterile solutions and sterile equipment were being manipulated, there was clutter including several plastic bins either containing alcohol wipes or the paper batch record contained within a plastic cover.

OBSERVATION 2

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

a). Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm only monitors viable air counts (b) (4) and during the (b) (4) cleanroom certification by an outside vendor; lastly on 10/29/14.
b). Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions. The firm only monitors non-viable air counts during the (b) (4) cleanroom certification by an outside vendor; lastly on 10/29/14.
c). The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. This monitoring is only performed (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	James A. Liubicich	James A. Liubicich, Investigator	05/06/2015

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d). The ISO 5 non-hazardous clean room and the ISO 7 hazardous clean room, the respective ISO 7 anterooms, and the unclassified surrounding areas are not continuously monitored for air pressure differentials during production. The only times readings are monitored are at (b) (4) for the ISO 5 clean room only and its anteroom. Pressure differentials are not monitored between the ISO 7 hazardous clean room and its anteroom, nor between that anteroom and the surrounding unclassified areas.

OBSERVATION 3
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

a). Sporicidal agents are not used to disinfect the ISO 5 surfaces.

b. No disinfectant effectiveness studies have been performed to determine if disinfection agents are effective in a) septic processing areas. Disinfectants used (b) (4) are (b) (4) on a (b) (4) basis and (b) (4) which is used (b) (4).

OBSERVATION 4
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

a). (b) (4) are prepared for various products from non-sterile ingredients. These (b) (4) can be held for up to (b) (4) days as for Papaverine HCL. Your firm has not conducted any hold time studies to support the stability/sterility over the time periods that (b) (4) are stored.

b). You have not validated the (b) (4) sterilization used for two of your injectable drug products, such as Triamcinolone Suspension 40mg/ml Injection, within your (b) (4)

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OBSERVATION 5
Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Your firm does not test every sterile drug lot produced for sterility or endotoxins. Sterile drugs produced from non-sterile components are tested for sterility and endotoxins only for batches (b) (4) .

OBSERVATION 6
The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

There are no separate facilities, for processing operations, to prevent contamination from the beta-Lactam injectable drug that you process – Ceftazidime syringe. This beta-Lactam powder, which is contained in glass vials, is processed in the same ISO 5 hood as are sterile injectable non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent powder spill would not contaminate other sterile drug products.

OBSERVATION 7
There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates.

Your firm has not tested for sterility or potency over the assigned Beyond Use Date (BUD) for all of your sterile drug products. For example, your firm has not conducted complete testing to support the BUDs such as 180 days for Estradiol subcutaneous pellets at room temperature. You have no stability studies to assure that the sterility and potency will be maintained over the time period of the BUD.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."