DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/10/2016-3/18/2016*
	FEI NUMBER 3012200488

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael B. Bitar , Part Time Pharmacist	
FIRM NAME Meditech Laboratories, Inc	STREET ADDRESS 3200 Polaris Ave, #27
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89102	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

- Your firm has not performed smoke studies under dynamic conditions to demonstrate unidirectional air flow patterns in the ISO 5 LAFW and ISO 7 clean room where injectable drug products are prepared. According to the reports provided by the contract vendor who performs the clean room (b) (4) ; however, your firm does not have any documentation (i.e. video) to demonstrate the air flow patterns of the ISO 5 LAFW and the ISO 7 clean room.

- During the inspection of the firm's clean room facility, we observed that the ISO 5 LAFW HEPA filters appeared to be discolored. The firm's management stated that the stains were likely due to chemicals from disinfectant sprays and the stains had been there since late 2014.

- Your firm's clean room humidity is not controlled. Humidity is only (b) (4) There was no documented clean room temperature and humidity recording in 2015. There was also no documented recording in January 2016. Temperature and humidity monitoring resumed in February and March 2016. From January 2015 to January 2016, about (b) (4) lots of sterile injectable were prepared and released by your firm.

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- Pressure differential (PD) of your firm's clean room facility is not monitored on each day a batch of sterile drug is prepared in the ISO 5 area. The last PD monitoring in 2015 was performed in (b) (4) There was no documented monitoring from May to December 2015. There was also no documented PD monitoring in January 2016. PD monitoring resumed in (b) (4) From May 2015 to January 2016, about (b) (4) ots of sterile injectable were prepared and released by your firm.

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

- Each batch of your firm's sterile drug products is tested for potency by a contract testing laboratory. However, there is no analytical method validation performed for potency method used in testing of your firm's sterile drug products (Formulation 1 to 9) to assure method suitability.

- On approximately 02/09/2016, Batch # 020716-0 of Formula F0 was released and dispensed without sterility, potency, or endotoxin testing performed on the lot.

OBSERVATION 3

Drug product production and control records, are not approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, your batch records are not approved prior to final product release. On 03/10/2016, we observed the following products in the freezer that is designated for released products:

- (b) (4) vials of Formulation F9, Lot 022416-9, produced on 02/24/2016.
- (b) (4) vials of Formulation F4, Lot 022316-4, produced on 02/23/2016.

During our review of the batch records of these two lots, we observed that the portion of the batch record indicating if testing records were received and if the batch was released was not completed. The pharmacist name and date of batch release was also not completed. Despite the absence of this information, these batches were released and the following amount was dispensed and shipped to patients:

- (b) (4) vials of Formulation F9, Lot 022416-9, was dispensed and shipped to patients.
- (b) (4) vials of Formulation F4, Lot 022316-4, was dispensed and shipped to patients.

OBSERVATION 4

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the garments and protective apparel worn by your sterile drug operator is inadequate. Your clean room gowning consists of non-sterile shoe covers, non-sterile hair net, non-sterile face mask, non-sterile lab coat, and sterile gloves.

OBSERVATION 5

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

Specifically, each batch of your firm's sterile drug product is tested for sterility by a contract testing laboratory. However, testing by the contract laboratory does not appear to meet all the requirements for

method suitability specified in relevant compendial methods. For example, there is no method suitability validation performed in testing of your firm's sterile drug products (Formulation 1 to 9).

OBSERVATION 6

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

Specifically, your firm's environmental monitoring operations are inadequate for the following:

- Your firm's environmental and personnel monitoring are not performed each day that a batch of sterile drug is produced in the ISO 5 clean room. Instead, they are performed on (b) (4) (b) (4) (b) (4)
- There is a lack of documented evidence that your firm's environmental and personnel monitoring program was adequately performed. For example, the last documented surface monitoring for (b) (4) was performed in (b) (4) From July 2015 to date, there was no documented surface monitoring performed by your firm. In addition, the last documented personnel monitoring in (b) (4) was performed in (b) (4) From March 2015 to December 2015 there was no documented monitoring. Personnel monitoring resumed in (b) (4) but stopped in (b) (4) From May 2015 to date, about (b) (4) lots of sterile injectable were produced and released by your firm.
- Your firm has no written descriptions, maps, or justifications for how each environmental monitoring location was determined.
- Growth promotion was not performed for each lot of (b) (4) (b) (4) media for environmental and personnel monitoring.
- Your firm performs media fills (MF) (b) (4) (b) (4) (b) (4) but did not simulate production process under routine operating conditions. Your firm's "Sterile compounding standard operating

procedures", updated 10/10/2015, item # 22 under Aseptic Technique states, "(b) (4) (b) (4) ". For example, the current media fill procedure does not include (b) (4) of weighing out individual API, (b) (4) . Also, the largest batch prepared by your firm was abou(b) (4) vials while only (b) (4) Additionally, your firm could not locate any of your pharmacists(b) (7)(C), (b) (8) records for the last two years, except for(b) (4), (b) (6), (b) (7)(C) performed on(b) (4)

OBSERVATION 7

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, your firm's sterile products are marketed for multi-dose use while stored in refrigerated conditions. Your firm has not performed any studies to support that your container closure systems are able to adequately protect the product from contamination during multi-dose use in refrigerated storage conditions.

OBSERVATION 8

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

Specifically, your firm lacks documented cleaning and disinfecting of the clean room facility where sterile injectable are compounded. For example,

- For ISO 5 LAFW: The last documented cleaning in 2015 occurred in(b) (4) Afterwards, there was no documented cleaning from May 2015 to December 2015. Additionally, there was no documented cleaning in January 2016. There were entries in the cleaning logbook from(b) (4) but no cleaning records for the month of March 2016. Also, the SIO 5 LAFW is cleaned(b) (4)with(b) (4) Your firm uses (b) (4)

while the (b) (4) manufacturer labeling states the (b) (4) (b) (4)

- For ISO 7 clean room and ante room: The last documented cleaning for 2015 occurred in (b) (4) Afterwards, there was no documented cleaning from May 2015 to December 2015. Additionally, there was no documented cleaning in January 2016. There was (b) (4) (b) (4) nd again, no documented cleaning for the month of March 2016. Also, the SIO 7 clean room and ante room are cleaned (b) (4) (b) (4) with (b) (4) Your firm applie (b) (4) while the (b) (4) (b) (4) manufacturer labeling states the (b) (4)

From May 2015 to date, approximately (b) (4) lots of sterile injectable were produced and released by your firm.

OBSERVATION 9
Written distribution procedures are not followed.

Specifically, according to your firm's "Sterile compounding standard operating procedures", updated 10/10/2015, under "(b) (4) ", a (b) (4) (b) (4) According to your firm's Shipping Clerk, the firm does not ship sterile products with any (b) (4) .

In addition, this procedure is inadequate because it requires (b) (4) (b) (4) . However, your firm's sterile product vials contained inside the shipping box have labels that instruct patients to "STORE UNOPENED VIALS IN FREEZER". Your firm's sterile products' Beyond-Use Dates are based on frozen storage conditions and not refrigerated storage conditions. The contradicting labels may mislead patients to store the sterile products in refrigerated conditions instead of frozen conditions which may affect the product's Beyond-Use Date.

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OBSERVATION 10

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

- Your firm has no justifications for assigning expiration dates on the finished drug product beyond the expiration date of the API. For example, the finished sterile drug product Lot # 011716-3 was prepared using API Atropine Lot #(b) (4) that expired on (b) (4) . Lot # 011716-3 was assigned a BUD of 04/16/2016 which was beyond the Atropine expiration date. Lot # 011716-3 was subsequently released and dispensed to patients on 01/19/2106. Between 01/17/2016 and 03/17/2016, abou(b) (4) prescriptions were filled using Lot # 011716-3. Other Lots that have expiration dates beyond the Atropine (b) (4) expiry including but are not limited to Lot # 011916-1, Lot # 012216-2, Lot # 012416-3, and Lot # 020316-1.

- Your sterile products bear a 45 day Beyond-Use Date(BUD) in frozen conditions. However, your labeling allows a patient to store sterile products for up to 28 days in refrigerated conditions after the first dose. Your firm does not have stability data to support storage under these conditions.

OBSERVATION 11

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, your firm cleans and depyrogenates glassware for the mixing of active pharmaceutical ingredients (API) during sterile drug preparation. During the inspection, we observed depyrogenated (b) (4) The (b) (4) were not labelled with date of depyrogenation and there was no validated expiration date assigned to the depyrogenated glassware that is intended for aseptic processing.

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OBSERVATION 12

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

- Your firm uses the "Quality Related Event" Log to track consumer complaints. This log contains three complaints in which the drug product was either not working or not working well. These complaints were dated 11/30/2015, 12/15/2015, and 01/06/2016. However, investigations were not performed on any of these complaints.
- We reviewed the two potency tests performed by a contract testing laboratory on FORMULA-2, Lot# 110115-2, and found the two potency test results to be superpotent. The two potency tests were performed on 12/01/2015 and 12/31/2015 with resulting Prostaglandin potency level at 117% and 122%, respectively. Your firm did not perform an investigation into these failed test results.
- Isolates recovered from environmental and personnel monitoring were not identified to species level to detect the presence of yeast, mold, or Gram negative pathogens.

OBSERVATION 13

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, your firm does not have written procedures regarding the documentation of consumer complaints, consumer complaint investigations, and investigation of failed test results.

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Las Vegas, NV 89102	Producer of Sterile Drugs

3/10/2016(Thu),3/14/2016(Mon),3/15/2016(Tue),3/16/2016(Wed),3/17/2016(Thu),3/18/2016(Fri)

3/18/2016

X Eileen A Liu

Eileen A Liu
Microbiologist
Signed by: Eileen A. Liu -S

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