DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3001298034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Larry D. Stephens, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Medaus, Inc.	6801 Cahaba Valley Rd Ste 116
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Birmingham, AL 35242-9609	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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

(a.) The firm has not conducted equipment qualification for the (b) (4) used to (b) (4) sterilize the following finished products Bethamethasone Acet/NAPO4, Dexamethasone LA 8 mg/mL, Triamcinolone Acet 60 mg/mL Inj Susp, all of which are made from non-sterile drug components.

(b.) The firm has not performed (b) (4) of the (b) (4) used to (b) (4) all injectable solution drug products made from non-sterile drug components.

OBSERVATION 2

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

We observed that the apparel worn by personnel who were producing injectable drug products in the ISO-7 cleanroom did not cover all skin areas on the forehead, around the eyes, and on the necks of the workers. Hoods and goggles were not used. The hairnets, beard covers, face masks, and disposable lab coats that were worn were non-sterile items. The workers were gowned as described in the firm's written procedure P&P No. 7.040, "Gowning."

OBSERVATION 3

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

The firm's media-fill process does not adequately simulate the aseptic processing steps which are used by the operators to produce injectable drug products. Specifically, the firm's media fill procedure, "Media-Fill Test Procedure for CSP Sterilized by (b) (4)," instructs the operator to (b) (4)

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(b) (4) [redacted]. However, the process which is actually used to produce all of the firm's injectable drug products is: to (b) non-sterile drug solutions (b) (4) into sterile (b) (4) bottles, to then open the bottles multiple times, making multiple entries into the bulk drug solutions using sterile tubing, and to then fill pre-sterilized vials using a commercial pump/filling machine. (There are no additional sterile (b) (4) steps after the multiple entries into the bulk drug solution.)

OBSERVATION 4

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

Specifically:

(a.) The firm's environmental monitoring program does not assess the routine processing environment. In the ISO-5 hoods, environmental monitoring for viable and non-viable airborne particulates and for surface bioburden, is performed at (b) (4) (b) (4) intervals under static conditions; however, (b) (4) is not an adequate frequency of environmental monitoring for the production of injectable drug products via aseptic processing.

(b.) The firm's environmental monitoring program does not assess the routine processing environment. In the ISO-7 cleanroom, environmental monitoring for viable and non-viable airborne particulates and for surface bioburden, is performed at (b) (4) intervals under static conditions; however, (b) (4) is not an adequate frequency of environmental monitoring for the production of injectable drug products via aseptic processing.

(c.) The firm's glove fingertip bioburden monitoring of operators who perform work in the ISO-5 hoods does not assess the glove bioburden levels under routine processing conditions. The glove fingertip monitoring is performed at (b) (4) intervals; however, (b) (4) is not an adequate frequency of glove fingertip monitoring for the production of injectable drug products via aseptic processing.

OBSERVATION 5

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

Specifically:

(a.) No monitoring is performed of the air pressure differential between the ISO-7 cleanroom and the adjacent ISO-8 anteroom/gowning room. No gauges for measuring room air pressures are present in the facility. There are no alarms for alerting personnel of potential air-pressure differential deviations.

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(b.) No smoke studies have been performed to verify that laminar airflow conditions exist inside the ISO-5 hoods, which are used for the production of injectable drug products.

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OBSERVATION 6

Drug products are not stored under appropriate conditions of temperature and light so that their identity, strength, quality, and purity are not affected.

Specifically, on 03/18/2013, the lots of bulk in-process injectable drug product identified below stored in (b) (4) drug containers, containing drug components, were observed to be stored on the counter top inside the ISO 7 room at ambient room temperature and/or without light resistant protection. Management explained it is a normal practice for these (b) (4) containers to be placed on the counter [redacted] (b) (4) to fill unit dose orders.

Products labeled "Refrigerate" and "Protect from Light" stored in (b) (4) containers includes:

1. Methyl B12 10 mg/mL Lot 1302122-35 BUD 8/11/13
2. Lipo-Injection w/ Lidocaine Lot 130315-08 BUD 09/11/13
3. Lipo #4 w/ Cyano B12 1 mg/mL Lot 1301157-67 BUD 07/14/13
4. B-Complex 100 (PE) Lot 130228-40 BUD 5/29/2013
5. Magnesium Chl 200 mg/mL Lot 130307-60 BUD 09/03/13
6. 2-NA Ascorbate 500mg/mL Lot 130313-34 BUD 09/09/13
7. DMSO Lot 121205-56 BUD 06/03/13
8. Calcium Sodium EDTA 300mg/mL Lot 130306-50 BUD 09/02/13
9. Calcium Chl 10% (PE) Lot 130308-34 BUD 09/04/13
10. Methyl B12 1000 MCG Lot 130312-21
11. Hydroxy B12 1000 MCG Lot 130228-26 BUD 8/27/13
12. MIC/B Complex Lot 130123-67 BUD 07/28/13
13. Methyl B12 200 MCG/mL Lot 130129-35 BUD 07/28/13
14. (3-100 mL vials) Testosterone Cyp 200 mg/mL Lot 130315-8 BUD 9/11/13
15. Sweet-MCBFIT Allen Lot 121213-51 BUD 6/11/13
16. Hydrogen Peroxide 3% Lot 130307-70 BUD 9/03/13
17. Express IV Nutrients Lot 130305-54 BUD 9/01/13
18. Methyl B12 1000 MCG Lot 12114-80 BUD 5/13/13
19. (2-30mL vials) Lipo-Injection w/ Methyl B12 500 MCG Lot 130301-32 BUD 08/28/13

Product labeled "Refrigerate" stored in an (b) (4) container includes:

1. Allen IV Nutrient Lot 130205-33 BUD 8/04/13

Products labeled "Protect from Light" stored in (b) (4) containers includes:

1. Methyl B12 25mg Lot 130227-17 BUD 08/26/13
2. Pyridoxal 100 mg/mL Lot 130301-19 BUD 9/28/13

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OBSERVATION 7

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm does not have any hold time data to support the completion of each production phase for any of your injectable drug products (when not being held under refrigerated or light resistant conditions) including but not limited to preparation of the original batch of product (b) (4) , and multiple transfers of the product into unit does vials from (b) containers, to assure the quality of all injectable drug products at your firm.

OBSERVATION 8

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

Specifically, sterility testing is performed on each original large batch of all injectable drug solutions made from non-sterile components after being transferred into (b) containers. However, sterility testing is not performed on any batches of drug product filled from those (b) containers after it has been reopened and exposed to the ISO 5 environment for filling of unit dose vials.

OBSERVATION 9

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

Specifically, Dexamethasone 8mg/mL Lot 130118-11 (Beyond Use Date: July 17, 2013) was released for dispensing on 01/18/2013, but sterility testing results were not received until 02/06/2013. Dexamethasone 8mg/mL Lot 120927-7 (Beyond Use Date: March 26, 2013) was released for dispensing on 09/27/2012, but sterility testing results were not received until date 10/15/2012. Both lots were recalled after (b) (4) sterilization) biological indicator testing failed prior to the receipt of sterility results.

OBSERVATION 10

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically, the firm has not conducted stability testing nor has data to support any expiration dates (beyond use dates) for any injectable drug products produced. For example, there is no data to support the use of 6 month beyond use dates for Lipo Injection, Cyano B12, or Lipo w/ Methyl B12 w/ Preservative.

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OBSERVATION 11

Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and drug products used in the manufacture, processing, packing, or holding of drug products.

Specifically, the firm does not have any written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, drug products used in the manufacture, processing, packing, or holding of drug products. The firm does not perform supplier qualification to verify certificates of analysis for any drug components, drug product containers, closures, drug products used in the production, processing, packing, or holding all drug products at your firm.

OBSERVATION 12

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

Specifically, on 3/18/13, an operator producing injectable drug products in an ISO-5 hood was observed to move materials from the ISO-7 cleanroom zone into the ISO-5 zone without disinfecting the exterior surfaces of the materials before moving them into the ISO-5 zone. The materials moved into the ISO-5 area without disinfection were: a container of bulk drug solution, a package holding sterile tubing, and empty, pre-sterilized, stoppered vials.

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