DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Building 200, Suite 500 Nashville, TN 37217 (615)366-7801 Industry Information: www.fda.gov/oc/industry	03/07/2016 – 03/11/2016 FEI NUMBER 3001298034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Larry D. Stephens, Chief Operating Officer and Owner

FIRM NAME	STREET ADDRESS
Medaus, Inc.	6801 Cahaba Valley Rd., Suite 116
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Birmingham, AL 35242	Producer of Sterile Products

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

a) You failed to demonstrate control of your environment by exceeding action levels in the ISO 7 environment in August 2015 with 50 cfus and in February 2016 with 12 cfus of spore forming organisms and gram-positive organisms. You continue to produce sterile products without determining root cause and taking appropriate corrective action.

b) Surface and air (viable and non-viable) monitoring is not performed in the ISO 5 environment (laminar flow hood) each day sterile drug products are produced. Your firm only monitors the ISO 5 environment (b) (4) (b) (4)

c) Personnel monitoring (fingertip) is only performed (b) (4)

d) HEPA filters in the ISO 7 area have not been leak tested (b) (4)

e) Pressure differentials are not monitored between the ante room (ISO 8) and the non-classified area (warehouse) because there is no pressure gauge.

f) Certification of the ISO 7 and ISO 5 environment does not occur under dynamic conditions.

OBSERVATION 2

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

Specifically,

a) Your media fills do not the most challenging conditions to assure that sterile processing techniques are adequate to ensure the sterility of drug products, for example: quantities and different sized drug product containers.

b) You have not qualified, calibrated or performed (b) (4) sterilize hormone pellets.

c) You produce sterile injectables from non-sterile materials for the products, DMSO and Testosterone Cypionate, using (b) (4)

d) You do not always document the (b) (4) of your sterilizin (b) (4) Documentation of this (b) (4) does not include the actual (b) (4), only the word, "pass".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Claire M. Minden	Claire M. Minden, Investigator Jennifer Del Valle, Consumer Safety Officer	03/11/2016

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We also observed personnel (b) (4) from the ISO 7 to the ISO 5 (LFH) area in front of the red tape line without decontaminating with sterile (b) (4) The LFH have a red tape marking the (b) (4) to (b) (4) The tape is only (b) (4) and conceals contamination.

OBSERVATION 3
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the beyond use date of six months assigned to all except six of your sterile products which are 30 or 90 days is based on (b) (4) Sterility and endotoxin are not included in your studies to substantiate the beyond use date applied.

In addition, you visually inspect your products b (b) (4) (b) (4) to look for contamination.

OBSERVATION 4
Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

a) The design of the ISO 7 room cannot assure sterile operations. There are (b) (4) HEPA filters located approximately (b) (4) from the (b) return air vents in the ceiling. These same (b) (4) HEPA filters also have large metal bookshelves located directly below them possibly causing turbulence. Your last certification indicates lower velocity and presence of microorganisms that exceed action levels in the area below/around these HEPA filters where (b) (4) LFHs and (b) (4) are located.
b) We also observed air gaps around the swinging door from the ante room (ISO 8) to ISO 7 room.

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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.

Specifically, you do not conduct sterility, endotoxin and potency on all lots of sterile drug products.

In addition, the method, (b) (4), used by (b) (4) for endotoxin testing is not scientifically valid.

OBSERVATION 6

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

Specifically, employees were observed to wear non-sterile lab coats, masks, head covers and booties while producing sterile drug products. Clothing used does not cover neck or forehead of employee during aseptic operations.

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, you do not have any hold studies to support storing bulk held in (b) (4) (b) (4) containers after (b) (4) under (b) (4) prior to (b) (4). We also observed (b) (4) bottles that were partially used.

OBSERVATION 8

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

Specifically, you use non-sterile cleaning agents (b) (4) and (b) (4)) (b) (4) in the cleaning and sanitization of the ISO 7 room.

In addition, the sterile wipes you use to clean the ISO 5 (LFH) are labeled for use in (b) (4)

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OBSERVATION 9

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

Specifically, you do not use amber vials for any sterile drug products labeled to be protected from light.

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