DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	06/02/2015 - 07/21/2015* FEI NUMBER 3011581046

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William J. Kalman, President and Co-owner

FIRM NAME	STREET ADDRESS
Kalman Health & Wellness, Inc. dba Essential Wellness Pharma	4625 N University St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Peoria, IL 61614-5828	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

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 laminar air flow hood in which sterile drug products are produced and the HEPA filters for the rooms in which sterile drug production and gowning for sterile drug production occur are (b) (4) . The HEPA filters and grates for the hood and rooms are not cleaned or disinfected prior to sterile drug production.

b. Media fills are deficient as follows:

i. (b) (4) employees who produces sterile drug products, pharmacy technician (b) (6) has not conducted any media fills.

ii. The firm does not conduct media fills that replicate the process used to fill sterile drug products. Media fills are only conducted by (b) (4) whereas most sterile drug products are filled into open containers.

iii. Media fills do not include positive or negative controls. Also, the firm does not perform growth promotion on the media used.

iv. Media fill incubation temperatures are not recorded.

c. The (b) (4) sterilization of some bulk products has not been validated. For example, this includes Testosterone (b) (4) , Testosterone (b) (4) / Testosterone (b) (4) / Testosterone (b) (4) , Testosterone (b) (4) / Testosterone (b) (4) and Progesterone Injectable (b) (4) .

d. Smoke studies are not performed under dynamic conditions.

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OBSERVATION 2

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

Specifically,

The "rooms" in which sterile drug production and gowning for sterile drug production occur are separated from the area with air that is not HEPA filtered by plastic drapes (strips) which extend from the ceiling to just above the floor.

OBSERVATION 3

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

Specifically,

a. The HEPA filters and grates for the hood and rooms are not cleaned or disinfected prior to sterile drug production. The laminar air flow hood in which sterile drug products are produced and the HEPA filters for the rooms in which sterile drug production and gowning for sterile drug production occur are (b) (4) .

b. The disinfectants and towels used to disinfect the laminar air flow hood in which sterile drug products are produced are not sterile.

c. The firm does not routinely use sporicidal disinfectants in areas where sterile human and animal drug products are being produced. It used a sporicide (b) (4) and discontinued its use afterward.

OBSERVATION 4

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a. On 6/2/2015 I observed brown stains on the HEPA filter in the laminar air flow hood used in the production of sterile human and animal drugs.

b. Balances used to weigh active pharmaceutical ingredients (APIs) are not cleaned between the weighing of each API. Some

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APIs weighed with these balances include HCG, cyclosporin, tacrolimus, progesterone, and testosterone, which are listed in SOP 8.055 "List of Potentially Hazardous Chemicals- Drugs".

c. The firm cleans glass beakers and stir bars used to produce some bulk sterile drug product (b) (4) with (b) (4) . The firm has not tested the water to determine its pyrogen levels.

OBSERVATION 5

Approved components and closures are not retested or reexamined as appropriate for identity, strength, quality and purity after exposure to conditions that might have an adverse effect with subsequent approval or rejection by the quality control unit.

Specifically,

a. Each bag of Sterile (b) (4) used as a component in human and animal sterile drug products is normally stored for a (b) (4) Each time (b) is withdrawn from the bag's port with (b) (4) There is no data demonstrating that the (b) remains sterile throughout this period. Also, no records are made of the initial and subsequent times each bag is opened.

b. Sterile caps for pre-filled syringes are used after the container in which they are packaged is (b) (4) . These caps are received in (b) (4) each of which typically lasts for (b) (4) after first having been opened. In this time period the (b) (4) is usually (b) (4) There is no data demonstrating that the caps sterile throughout this period. Also, no records are made of the initial and subsequent times each (b) (4) is opened.

OBSERVATION 6

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

a. There is no record that (b) (4) (b) (4) has been conducted on the (b) (4) all lots of sterile drug product which require (b) (4) . For example:

i. The formula worksheet for Sermorelin/Lidocaine Injection 1000mcg/ml/0.2% lot 052815, made on 5/28/2015 from non-sterile powdered API, states that the product is to be (b) (4) yet there is no record of the (b) (4) used in this lot having been (b) (4) (b) (4) .

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ii. The formula worksheet for HCG/Lidocaine Injection 1000 U/ml/0.2% lot 052815, made on 5/28/2015 from non-sterile powdered API, states that the product is to be (b) (4) yet there is no record of the (b) (4) used in this lot having been (b) (4) (b) (4).

iii. The formula worksheet for HCG/Lidocaine Injection 1000 U/ml/0.2% lot 052615, made on 5/26/2015 from non-sterile powdered API, states that the product is to be (b) (4) yet there is no record of the (b) (4) used in this lot having been (b) (4) (b) (4).

b. No records are made when bulk sterile drug products are (b) (4) sterilized.

c. No record is made when visual inspections of sterile human and animal drug products are conducted. Furthermore, Formula Worksheets for such products do not include conducting visual inspections as production steps.

OBSERVATION 7

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

Specifically,

a. The environmental and personnel monitoring covering the firm's production of sterile human and animal drug products is deficient as follows:

i. The firm does not perform surface monitoring and personnel monitoring every time sterile drugs are produced. Surface monitoring and personnel monitoring occur (b) (4). When they do occur they are not conducted under worst case conditions; surface monitoring occurs (b) (4) and personnel monitoring occurs (b) (4).

ii. The only air monitoring for viable particulates that the firm does in the laminar air flow hood where sterile drugs are produced is a (b) settle plate approximately (b) (4).

iii. The firm does not monitor the air in the laminar air flow hood where sterile drugs are produced for non-viable particulates during production or active conditions.

iv. The firm only monitors the air in the laminar air flow hood where sterile drugs are produced for non-viable particulates during passive conditions approximately (b) (4).

b. Pressure differentials between the room in which sterile drugs are produced, the room in which gowning for sterile drug production occurs, and the room in which non-sterile drugs are produced in unclassified conditions are not monitored.

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OBSERVATION 8

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

Specifically,

The garb worn by personnel while conducting aseptic filling of sterile human and animal drug products does not adequately protect the products as follows:

a. The gown, hair net, and mask that personnel wear while producing sterile drug products are not sterile.

b. The hair net and mask, which covers the nose, mouth, and chin, leave skin on the face and neck exposed.

c. The gown is (b) (4) each day. It is stored in the room where gowning occurs on a hook when not being worn.

OBSERVATION 9

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

Specifically,

The firm has no evidence that its (b) (4) sterilizes the glass eye droppers into which it fills some of its sterile human and animal drug products. Furthermore, no records are made of this process.

OBSERVATION 10

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

Certificates of Analysis for components used to produce sterile human and animal injectable drug products do not always indicate that they have been tested for pyrogens or bacterial endotoxins. For example:

a. Hydroxyprogesterone Caproate (b) (4), which was used as a component in Hydroxyprogesterone Caproate Injection (Castor Oil) 250 mg/ml lot 052615, does not list pyrogen or bacterial endotoxin test results on its Certificate of

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Analysis.

b. Methylcobalamin (b) (4) , which was used as a component in Methylcobalamin Injection (Preservative Free) 5000 mcg/ml lot 052815, does not list pyrogen or bacterial endotoxin test results on its Certificate of Analysis.

c. Sermorelin (b) (4) (b) (4) , which was used as a component in Sermorelin Injection 9 mg/10 ml lot 052915, does not list pyrogen or bacterial endotoxin test results on its Certificate of Analysis.

OBSERVATION 11

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

Specifically,

Sterile human and animal drug products are not always tested for sterility or pyrogens. For example:

a. Sermorelin Injection 1000 mcg/ml lot 051515, produced 5/15/2015, was not tested for sterility or pyrogens.

b. HCG 1000 U/ml lot 051515, produced 5/15/2015, was not tested for sterility or pyrogens.

c. Cyclosporine Ophthalmic Solution 2% lot 051515, produced 5/15/2015, was not tested for sterility.

OBSERVATION 12

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

Specifically,

Sterile human and animal drug products are not always tested for potency. For example:

a. Sermorelin Injection 1000 mcg/ml lot 051515, produced 5/15/2015, was not tested for potency.

b. HCG 1000 U/ml lot 051515, produced 5/15/2015, was not tested for potency.

c. Cyclosporine Ophthalmic Solution 2% lot 051515, produced 5/15/2015, was not tested for potency.

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OBSERVATION 13

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

Specifically,

The firm does not always have data to support the expiration periods it assigns to its sterile human and animal drug products. For example:

a. Some of the firm's sterile drug products have not been stability tested at all, such as MIC Injection (expiration period of 90 days under refrigeration) and Acetylcysteine Ophthalmic Drops 10% (expiration period of 30 days under refrigeration or 45 days frozen).

b. There is no evidence to support any of the (b) (4) day expiration periods assigned to the firm's bulk injectable sterile drug products once they have been punctured for dispensing.

c. There is insufficient evidence to support the expiration periods assigned to some of the firm's sterile drug products. For example:

i. HCG Injection 10,000 U/ml has an expiration period of 30 days refrigerated yet it has not been tested beyond (b) (4) days for sterility and (b) (4) days for endotoxins. It has never been tested for potency.

ii. Cyclosporin Ophthalmic Solution 1% has an expiration period of 90 days refrigerated yet it has not been tested beyond (b) (4) days for sterility.

d. None of the firm's sterile drug products have been stability tested for antimicrobial effectiveness; all but one contain one or more preservatives.

OBSERVATION 14

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

Specifically,

a. The (b) (4) that the firm uses to (b) (4) (b) (4) the (b) (4) that it has used to sterilize human and animal drug products has not been calibrated.

b. The thermometer in the (b) (4) that the firm uses to sterilize bulk human and animal drug products has not been

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calibrated.

c. The balances the firm uses for weighing non-sterile components for use in sterile human and animal drug products are not calibrated within their ranges of use. The lowest standard weight used in their most recent calibrations was (b) (4) yet:

i. On 5/14/2015, one of these balances was used to (b) (4)
On 5/15/2015, one of these balances was used to weigh (b) (4) HCG Injection 1000 U/ml lot 051515.

ii. On 5/11/2015, one of these balances was used to weigh (b) (4)
(b) (4) On 5/15/2015, (b) (4) were used as a component in Cyclosporin Ophthalmic Solution 2% lot 051515.

iii. On 5/7/2015, one of these balances was used to weigh (b) (4)
On 5/15/2015, one of these balances was used to weigh (b) (4) Sermorelin Injection 1000 mcg/ml lot 051515.

OBSERVATION 15

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

No components used in human and animal sterile drug products are tested. Furthermore, Certificates of Analysis for these components are not reviewed, except in cases in which active pharmaceutical ingredient (API) activity affects the quantity of API used in production.

*** DATES OF INSPECTION:**
06/02/2015(Tue), 06/03/2015(Wed), 06/04/2015(Thu), 06/05/2015(Fri), 06/24/2015(Wed), 07/13/2015(Mon), 07/14/2015(Tue), 07/21/2015(Tue)

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