DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	07/31/2014 - 08/08/2014* FEI NUMBER 3004575469

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Scott T. Popyk, R.Ph, President

FIRM NAME	STREET ADDRESS
Health Dimensions, Inc.	39303 Country Club Dr. Suite A26
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Farmington Hills, MI 48331-3482	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 OBSERVED:

OBSERVATION 1

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

Specifically,

A. Adequate aseptic process simulations (media fills) have not been performed under representative worst case aseptic processing conditions to assure the sterility of drug products. To date, media fills conducted for operators consist of drawing 25mL of non-sterile media into three 30mL syringes, transferring 5mL from each syringe into three 10mL vials as a control, aseptically attaching a 0.2um sterile filter and 20-gauge needle to each syringe, and injecting 10mL of sterile filtered media from each syringe into two stoppered 10mL vials for a total of six vials of sterile filtered media which are then incubated. Examples of aseptic processing operations at your firm that are not reflected in media fills include the following:
   i. During production of Methylcobalamin injectable in 5 mL vials lot 06242014+383669, the product is sterile filtered into open, unstoppered vials which are then manually stoppered.
   ii. Production of impotence injections lot 07312014+387256 was observed to include the use of vent needles and filter sterilized process nitrogen gas after sterile filtration and filling the pre-stoppered vials via needle and syringe.

B. The environmental monitoring (EM) program is inadequate in that:
   i. Active viable EM is not performed during every drug production shift in the critical areas. Only one active viable air sample is routinely collected each week from each ISO 5 workbench.
   ii. Non-viable particulate (NVP) EM is not performed during every drug production shift in the critical areas. Only one NVP sample is routinely collected each week from each ISO 5 workbench.
   iii. Viable surface monitoring is not performed during each drug production shift in the critical areas. Only one surface sample is routinely collected each week from each ISO 5 workbench.

   However, sterile drug production activities routinely occur Mon-Fri approximately 7:00am-4:30pm.

C. The materials sanitization and transfer procedures are inadequate in that no sanitization step occurs when materials are transferred from the ISO 7 buffer room environment to the ISO 5 workbenches. Prior to transfer into the ISO 7 buffer room, a sanitization of material surfaces is performed with a 2% bleach solution in the ISO 8 preparation room. Materials stored in the ISO 7 buffer room and waiting use are not additionally protected from the ISO 7 environment prior to

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	Jeffrey D. Meng, Investigator 	08/08/2014

transfer into the ISO 5 workbenches. A review of video of the recent smoke study of the ISO 7 buffer room revealed that air from the room HEPA filters does not uniformly sweep over materials and appears to eddy near areas where materials are temporarily stored.

D. The gowning at your facility is inadequate in that the sterile garb worn by operators does not cover all exposed areas. Observation of operators working at the ISO 5 workbenches revealed that the gowning hood and mask do not provide adequate facial coverage allowing exposure of the skin around the eyes and forehead. Additionally, during two instances of personnel fingertip monitoring observed on 7/31/14, after contacting the media touch plates in the ISO 5 workbenches, operators removed and replaced their gloves within the workbench exposing the skin of their hands to the ISO 5 environment.

E. Viable surface EM and personnel fingertip monitoring is performed using TSA plates that do not contain disinfectant neutralizers. For example, TSA plate lot 1003233420.

F. Aseptic practices and techniques observed at your facility are inadequate in that during processing of intrathecal product lot 07312014+387283, the operator was observed to rest their hand on the ISO 5 work surface followed by the performance of aseptic manipulations without sanitization of their hands.

Sterile products produced under such conditions include:
Methylcobalamin pre-filled syringe lot 07092014+385142
Methylcobalamin 5 mL vial lot 06242014+383669
Intrathecal (hydromorphone and bupivacaine) injectable lot 07312014+387283
Impotence injectable 07312014+387256

OBSERVATION 2

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

Specifically,

Maximum sterile hold times for preservative free stock formulations is not validated. For example, sterile, preservative free bupivacaine lot 05292014+381063 was produced on 5/29/14 in 10 mL syringes with a BUD of 9/26/14. This lot was used, in part, to formulate intrathecal product lot 07312014+387283 which was then sterile filtered from a syringe into an open, unstoppered 50 mL vial which was then manually stoppered, capped, crimped, and autoclaved.

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OBSERVATION 3

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

Specifically,

Continuous differential pressure monitoring of the aseptic process suite is not performed. Differential pressure monitoring of the ISO 7 buffer room, ISO 7 ante room, and ISO 8 preparation room is only logged once per day.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Examples of lots of sterile products produced that are not tested for potency, sterility, and endotoxins.

i. Impotence injection lot 07312014+387256 in 1 mL vials with a lot size of 10 vials.
ii. Intrathecal (hydromorphone, bupivacaine, and clonidine) preservative free injection lot 07312014+387283 in a 50 mL vial with a BUD of 8/22/14. This intrathecal formula has a general BUD of 60 days after the compounding date if none of the BUDs of the stock components is earlier.

OBSERVATION 5

Complaint procedures are deficient in that written complaint records are not maintained in a file designated for drug product complaints.

Specifically,

There is no system to easily permit a systematic review of product quality related complaints. Clear adverse events are captured within the CADER (compounding adverse drug event reporting) system. However, the majority of patient inquiries and communications regarding product quality are noted within each patient's individual electronic profile along with other miscellaneous information.

*** DATES OF INSPECTION:**
07/31/2014(Thu), 08/01/2014(Fri), 08/04/2014(Mon), 08/08/2014(Fri)

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