DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	02/19/2013 - 02/22/2013
	FEI NUMBER 3004483463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jacob J. Beckel, CEO

FIRM NAME	STREET ADDRESS
Anazaohealth Corporation	5710 Hoover Blvd
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33634-5339	TYPE ESTABLISHMENT INSPECTED Producer of sterile 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 are not established, written, and followed.

Specifically,

The Pain Management media fills do not simulate production processes under normal operating conditions. Some deficiencies include but are not limited to:

a) SOP P-403 "Pain Management Premix process verification of sterile compounding fill" and SOP P-402.2 "Pain Management Media Fill and Process Verification" is deficient in that:
   1. The operator mixes the non-sterile (b) (4) media powder in an uncontrolled area instead of the ISO 7 area where non-sterile powders are handled during routine production.
   2. The filled beaker where this media is prepared is sanitized (b) (4) times with (b) (4) and (b) (4) prior to entering it into the ISO 7 area and ISO 5 hoods thus exposing the open media to disinfectants.
   3. Growth promotion tests are not conducted on the media used for media fills.
   4. **As per SOP P-403**, no environmental monitoring, i.e. fingertip, air and surface, is conducted during media fills.
   5. SOP P-402.2 requires the removal of the (b) (4) sterilizing filter during media fills of "Medium risk" products thus not representing actual production operations.
   6. The media fills did not incorporate worst case conditions such as longer process times, extended exposure of components, interruptions/breaks, or other applicable routine situations that could potentially impact the sterility of the product.

b) SOP P-403.1 "Pain Management High Volume Process Verification Media Fill" is deficient for the same reasons as stated above (a). In addition, the 10 ml sterile vials (commercially purchased) used in media fills do not represent the larger 50 ml vials used in regular production. Furthermore, the 50 ml vials and stoppers used in regular production are not appropriately sterilized and (b) (4).

c) Procedures and log books/forms governing the use of (b) (4) do not state the prescribed sterilization parameters (time, (b) (4), load, etc.) of any kind; no such work instructions were posted or readily available. It was

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observed that technicians used the wrong sterilization parameters for "wrapped" utensils of (b) (4) for (b) minutes instead of (b) (4) for (b) minutes as established by your firm. These utensils are used in the ISO 5 LAFW.

d) Some of the (b) (4) wrapped glassware and utensils available for aseptic operations were observed with brown stains, tears, and not identified with date of sterilization.

e) Bottles of sterile (b) (4) are re-filled in house with non-sterile (b) (4) in the nuclear clean room without obliterating the original "sterile" label of the bottle. These type of bottles were observed in ISO 7 & 8 areas of the nuclear and pain management clean rooms. It was not possible to differentiate between bottles containing sterile (b) (4) from those containing non-sterile (b) (4)

f) Prior to transfer into the clean rooms, packages of components, containers, closures and utensils are disinfected with (b) (4) spray; however, it was observed that the components were then wiped off with a dirty rag.

g) (b) (4) supplies are not identified with a unique number for each (b) (4) load/batch, and wrapped supplies may or may not be identified with a date of sterilization. Consequently (in Pain Management Pharmacy):

1. There is no assurance as to whether supplies from failed (b) (4) runs had been used in sterile preparation areas.
2. It could not be determined whether the firm's prescribed expiration date (b) (4) had been exceeded for undated wrapped sterile supplies used (of the dated supplies available, some were expired).

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 firm failed to validate the (b) (4) filters used to sterilize (b) (4) products produced by your firm from non-sterile components. In addition, your firm has not established pre-filtration bioburden limits in order to determine if it exceeds the maximum retention capability of the filter.

b) (b) (4) sterilization process parameters in use for liquid nuclear preparations differ from the validated processing parameters, in some cases ~~(extent unknown, pending receipt of additional records on 2-22-13)~~. Sterilization time and (b) (4) were both decreased, while (in some cases) container sizes and volumes were increased and "pig" shields were added. Further, the time and (b) (4) parameters used vary significantly from batch-to-batch, depending on which (b) (4) unit is used. These changes have not been validated to ensure sterility and other product quality attributes.

c) (b) (4) sterilization process parameters for dry supplies (beakers, stoppers) have not been validated, in some cases, depending on which (b) (4) unit is used. Said supplies are used in sterile ISO5 processing areas.

d) Some (b) (4) sterilization process validations (where performed) only demonstrated a 3-log kill (biological indicator

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(b) (4) population: 2.0 x 10^2), and initial bioburden has not been determined for the associated injectable preparations.

OBSERVATION 3

Samples taken of drug products for determination of conformance to written specifications are not representative.

Specifically, sterility samples are collected from a bulk stock solution in a beaker (b) (4), prior to transfer into (b) (4) into syringes. No finished drug product testing in its final container closure system is performed.

OBSERVATION 4

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

Specifically,

a) Surface and air monitoring of the ISO-5 classified laminar airflow workstations (LAFW) is not conducted at least daily, despite production of sterile drug products.

b) Personnel monitoring, including fingertip sampling, of operators involved in sterile operations of intrathecal drug products in the ISO-5 LAFW is not conducted at least daily.

c) The firm failed to investigate excursions in their environmental monitoring program whereby viable air samples within the ISO-7 classified compounding pharmacy were found to exceed Action Levels.

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OBSERVATION 5

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

Specifically,

a) Operators performing aseptic operations in ISO 5 hoods re-use sterile cloth gowns throughout a production day. As sampling of sleeves is not performed, your firm has no assurance that the sterility of the sleeves is maintained.

b) Large open packages containing multiple pairs of (b) (4) gloves were observed in the nuclear ISO 8 gowning area. These gloves are used in the nuclear clean rooms to perform aseptic operations. The bag is dated when opened but there are no controls to prevent their use in aseptic operations once sterility is compromised.

OBSERVATION 6

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

Specifically,

a) The suitability, efficacy, and limitations of disinfecting agents and procedures has not been assessed to ensure potential contaminants are adequately removed from surfaces in the ISO classified areas.

b) Routine cleaning procedures of the ISO-5 classified LAFW do not include the use of a qualified sporicidal cleaning agent at established frequencies.

c) Non-sterile wipes are used to clean the ISO 5 LAFWs.

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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, your firm lacked adequate data to support the 5-month expiration date (hold time) of the bulk sterile pre-mix bags for the preparation of intrathecal drugs.

OBSERVATION 8

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 assigns a 90-day expiration date to all intrathecal drug products without adequate stability data tested with stability-indicating methods.

OBSERVATION 9

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,

a) There is no data to demonstrate that the non-sterile 50cc amber glass vials and rubber stoppers repackaged by your firm in uncontrolled areas for sterilization by (b) (4) are sterile and free of pyrogens and particulates prior to being filled with Phosphatidylcholine solution for injection.

b) Rubber stoppers are routinely sprayed directly with (b) (4) in ISO 5 hoods prior to use in sterile operations to cap product vials of injectable drug products. There is no data to demonstrate that (b) (4) residue on the product contact surfaces of the stoppers would not alter the quality, purity and strength of the sterile drug product.

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OBSERVATION 10

Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval, and rejection of components, drug product containers, and closures.

Specifically, your firm accepts components (excipients), containers (glass vials, bags, syringes), and closures (rubber stoppers) without sampling and examination to ensure they are adequate for their intended use. In addition, your firm lacked written procedures and specifications for the control and acceptance of all containers and closures.

OBSERVATION 11

Test procedures relative to appropriate laboratory testing for pyrogens are not written and followed.

Specifically,

a) Each lot of (b) (4) cartridges for endotoxin testing is not qualified upon receipt to demonstrate it performs as intended.

b) Non-depyrogenated glass vials and rubber stoppers are used in the performance of endotoxin testing of all sterile injectable drug products.

OBSERVATION 12

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

Specifically,

a) (b) (4) calibration/testing is not required by the firm's procedures, and was not performed by the service technician during (b) (4) certifications.

b) (b) (4) timers have not been checked/calibrated, as required by the firm's procedure.

c) The calibration of thermometers used in Refrigerators # 5 & 6 in the nuclear processing areas expired on 3/24/12. These refrigerators were observed as containing multiple batches of sterile injectable products in glass vials awaiting test results or

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prescriptions before dispensing.

d) The thermometers in refrigerators located in the pain management area were not identified and lacked calibration dates.

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