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	05/22/2013 - 06/11/2013* FEI NUMBER 3010199183

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David Allen Newbaker, Co-owner

FIRM NAME	STREET ADDRESS
Main Street Family Pharmacy, LLC	126 East Main Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newbern, TN 38059	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 validation of the sterilization process.

Specifically, your firm has not validated any process used in the processing of injectable drug products. For example,

a) the (b) (4) used for (b) (4) sterilization of injectable drug products has no data to support its ability to sterilize products under its conditions of use. No biological indicators have been used and no (b) (4) studies have been conducted to determine proper (b) configuration. No documentation is maintained for critical process parameters, such as (b) (4).
b) the (b) (4) used for final product endotoxin and sterility testing has no continuous temperature monitoring. No positive or negative controls are utilized during testing to confirm results.
c) media fills are conducted on an (b) (4) basis under static conditions that are not representative of the firm's drug processing activities. Batches frequently range from (b) (4) which can produce up to (b) (4) individual units.
d) smoke studies have not been properly documented for the air patterns of the ISO 6 clean room or the three ISO 5 laminar air flow hoods used in the processing of injectable products. The firm only has schematic diagrams which show air flow patterns which were conducted under static conditions.
e) the lyophilization unit used to manufacture injectable drug products has not been validated.

OBSERVATION 2

Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

Specifically, no equipment cleaning, maintenance, or use logs are maintained for critical pieces of equipment. For example,

a) the (b) (4) used for (b) (4) sterilization of injectable drug products has no records to document what product lots have been (b) (4) and when they were (b) (4). No records exist to document the (b) (4) cleaning, disinfection, or maintenance of the (b) (4).
b) the (b) (4) used for sterility and endotoxin testing has no equipment use log to document which finished product lots or tests were performed. No records exist to document cleaning, disinfection, or maintenance of the (b) (4).

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c) the lyophilization unit used to lyophilize injectable drug products has no records to document what product lots were lyophlized and when they were lyophilized. No records exist to document sterilization, cleaning, or maintenance of the lyophilization unit.
d) the three ISO 5 laminar air flow hoods used in the processing of injectable drug products do not have use records to document which product lots were produced under each hood. No records exist to document cleaning, disinfection, or maintenance of the hoods.
e) the pressure monitoring system does not document the pressure differentials between the clean room, ante room, and unclassified room on a continuous basis. Per management, the pressure differentials are checked (b) (4) .

OBSERVATION 3

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) your firm does not use any type of sporicidal cleaning agent, inside or outside of the ISO 6 cleanroom, which contains three ISO 5 hoods used in the processing of injectable drug products.

On 5/22/13, we observed:
b) during processing of TPN and HCG, components were brought into the ISO 6 clean room from the uncontrolled environment and were then placed on the work surface of the ISO 5 hood, Hood #3, without being disinfected with sterile isopropyl alcohol.
c) apparent product splatter on the HEPA filter in Hood #3, a vertical laminar air flow hood, in the clean room.
d) apparent product splatter on and around the edges of Hood #3 in the clean room.
e) apparent product splatter on the light directly above the workbench in Hood #2 in the clean room.
f) apparent product splatter on the black paper used for visual inspections of drug products in Hood #3.
g) charred black debris and stains on the (hot plate/stirrers located in the ISO 5 Hoods #1 and #2.
h) three bottles labled as (b) (4) identified by the firm as containing a (b) (4) for cleaning stainless steel tabletops.
i) the motor used for the lyophilization unit, which is located in the ISO 6 clean room, was observed to have oil leaking. A paper towel was observed to be placed between the leaking motor and lyophilization unit to absorb the oil.

On 5/30/13, we observed:
j) apparent splatter on the front face of the trash can located in the clean room.
k) apparent splatter on the HEPA filter located in the ceiling of the clean room.
l) a gown intended for use in the clean room stored on a coat rack in the hallway of the uncontrolled environment beside a door leading outside.
m) an unidentified spray bottle containing a clear liquid in the ante room.

n) on 5/22/13 and 5/30/13, the workbench surfaces of the ISO 5 hoods were observed to be stained.

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OBSERVATION 4

There was a failure to handle and store drug product containers at all times in a manner to prevent contamination.

Specifically, on 5/22/13, vials intended for use for injectable drug products were observed to be stored opened to the environment for multiple hours in Hood #2. No drug product was being processed during this time period.

OBSERVATION 5

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

Specifically, on 5/22/13, during observation of processing operations in the firm's ISO 6 clean room and with processing occurring under the ISO 5 Hood #3, your employee was observed to have exposed legs, eye make-up, and studded earrings. The employee was observed to be wearing a surgeon's mask, which left exposed facial areas, and a non-sterile gown worn over street clothes. The firm was processing patient specific injectable drug products, Total Parental Nutrition (TPN) and Human Chorionic Gonadotropin (HCG), labeled as sterile during this time frame.

OBSERVATION 6

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, the wipes used to clean the workbench surfaces of the ISO 5 hoods and the gowns donned in the ISO 6 cleanroom are not sterile.

OBSERVATION 7

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

Specifically,

a) the ante room, which is approximately (b) (4) and leads into the clean room, is not of adequate size to allow for proper gowning of employees prior to entering the clean room. No mirror is available to assure hair net coverage, no space is provided for sterile glove donning, and the water faucet in the ante room is not hands-free.
b) the floor of the ISO 6 clean room is composed of (b) (4) pieces of flooring joined by caulking. On 5/30/13, the caulking was observed to be worn away, causing a crack to be present in the floor of the clean room.

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Samantha J. Bradley, Investigator
Marvin D. Jones, Investigator

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c) the ceiling above the exterior of the ISO 6 clean room is open to the uncontrolled room and, on 5/22/13, exposed insulation directly above the door leading into the ante room was observed.
d) on 5/22/13, stains were observed on the floor of the ante room by the trash can while the firm was processing. Per management, the ante room is cleaned on a (b) basis (b) (4) processing.

OBSERVATION 8

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

Specifically, your firm performs its own pest control and, on 5/30/13, two spiders were observed in the ISO 6 clean room. The firm has no written pest control procedures.

OBSERVATION 9

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

Specifically, hold times have not been established and validated for your drug products between processing steps. When filling drug products from stock solution into bulk vials and final product vials, management indicated the time between fills could be (b) (4) or (b) (4). No records exist to document hold times between filling finished product vials from bulk vials.

OBSERVATION 10

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

Specifically, your firm does not have written and approved procedures for the processing/packaging/storage of injectable drug products.

OBSERVATION 11

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, you did not investigate the failure of the injectable drug product methylprednisolone acetate, 40 mg/mL, with 1% lidocaine, Lot 071712dan, to meet its potency specification. Of the three vials submitted for testing, which were recieved by a contract testing laboratory on 8/14/12, one of the vials was recorded to have a result of 125.98% (50.39 mg/mL), with a

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specification of (b) (4) [redacted] No investigation was performed and no corrective actions were documented. Per management, this lot was not distributed and it was destroyed.

OBSERVATION 12

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

Specifically, finished drug product endotoxin and sterility testing is conducted on a random basis, with no scientifically justified schedule or plan. Since December 2012, your firm has produced approximately (b [redacted] injectable drug products batches. During the same time frame, your firm performed endotoxin and sterility tests on 15 finished drug products, resulting in a total of 14 endotoxin tests and 15 sterility tests.

OBSERVATION 13

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, finished product potency testing is conducted on a random basis, with no scientifically justified schedule or plan. Since December 2012, your firm has produced approximately (b [redacted] injectable drug product batches. During the same time frame, your firm did not perform potency testing on any finished drug products.

OBSERVATION 14

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

Specifically, your firm does not have stability data to support the expiration dates assigned to injectable drug products. Preservative free drug products are assigned a 3 month expiration date and drug products with preservative are assigned a 6 month expiration date.

OBSERVATION 15

Each lot of components, drug product containers, and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, your firm does not sample, test, examine or release each lot of component, drug product container, or closure prior to its use in the processing of injectable drug products.

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OBSERVATION 16

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, your firm does not have written and approved procedures in place for production and process controls.

OBSERVATION 17

Procedures describing the handling of all written and oral complaints regarding a drug product are not established and written.

Specifically, your firm has not established, written, and approved procedures for the handling of complaints related to your processed drug products.

OBSERVATION 18

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

Specifically, your firm does not perform routine calibration on equipment. For example,

a) the gauge used for (b) (4) testing of (b) used in the aseptic sterilization process has not been calibrated in the 3 years it has been in use.
b) scales are calibrated on an infrequent basis using an uncertified, single (b) weight without any documentation of the calibration activities. No linearity testing is conducted for the scales.

OBSERVATION 19

A sample which is representative of each lot in each shipment of each active ingredient is not retained.

Specifically, your firm does not maintain retain samples of process injectable drug products.

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OBSERVATION 20

Distribution records do not contain the lot or control number of drug product.

Specifically, your firm does not document the lot numbers of drug products which would permit traceability of distributed drug products.

OBSERVATION 21

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

Specifically, your batch production records are lacking the following information:

a) identity of individual major equipment used, such as scales used for weighing out components,
b) in-process and laboratory control results,
c) inspection of the packaging and labeling area before and after use,
d) a statement of actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing,
e) complete labeling control records, including specimens or copies of all labeling used,
f) any sampling performed,
g) identification of the persons performing and directly supervising or checking each significant step in the operation,
h) results of finished drug product label visual examinations,
i) a description of drug product containers and closures with lot numbers,
j) (b) (4) testing documentation, and
k) finished product lot numbers.

OBSERVATION 22

Rejected components are not controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically, your firm does not separate expired components from in-date components. For example,

a) on 5/22/13, a tote of expired drug products was observed to be stored beside in-date drug products intended for distribution.
b) on 5/22/13, expired (b) used for aseptic (b) sterilization of drug products were observed to be stored amongst in-date (b) intended for use.

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OBSERVATION 23

There is no quality control unit.

Specifically, your firm does not have a quality control unit that is responsible for the approval and rejection of all standard operating procedures, components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products.

OBSERVATION 24

GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, your firm does not provide its employees involved in the processing of injectable drug products with training in current good manufacturing practices (cGMPs).

OBSERVATION 25

There is a lack of written procedures assigning responsibility, providing cleaning schedules, and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, your firm does not maintain written and approved procedures for the cleaning/disinfection of equipment and materials.

*** DATES OF INSPECTION:**
05/22/2013(Wed), 05/23/2013(Thu), 05/24/2013(Fri), 05/28/2013(Tue), 05/29/2013(Wed), 05/30/2013(Thu), 05/31/2013(Fri), 06/01/2013(Sat), 06/10/2013(Mon), 06/11/2013(Tue)

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