DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street, NE Atlanta, GA 30309 Industry Information: www.fda.gov/oc/industry	12/10-13, 18,20/2012; 1/4,11,16,18/2013
	FEI NUMBER 3009925820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrica Stephens, R.Ph - Pharmacist in Charge/Owner

FIRM NAME	STREET ADDRESS
Medi-Fare Drug & Home Health Center, Inc.	300 W. Pine Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Blacksburg, SC 29702	Compounding Pharmacy

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) (WE) OBSERVED:

Observation 1. There is no assurance that containers, closures, and drug products are free from objectionable microorganisms.

Specifically,
(a). There is no documentation available of the (b) (4) validations conducted to ensure appropriateness for use prior to (b) (4) glassware and finished product.

(b). Section 5.3 of your "(b) (4)", P&P 8.040, dated 9/15/03 require that "monitoring data from each cycle shall be recorded to ensure that processes are performed properly and that all critical parameters are within specified limits during processing". Your firm does not maintain (b) (4) cycle printouts to show the cycle parameters were met. During the inspection, sterilization cycle printouts were requested but never received. In addition your "(b) (4) Use, Cleaning & Spore Testing Log" does not list the lot number of the articles being sterilized, lot number of biological indicators used within the load or document cycle parameters.

(c). There are no records documenting that procedures were followed in the (b)(4) verification of your (b) (4) cycle, per your procedure entitled, "(b) (4) Cycle Verification", SOP No. E.023.1, dated 1/11/12. During the inspection, management stated that (b)(4) a biological indicator is placed into a load cycle and at the (b) (4) of that cycle, the BI is sent to (b) (4) for verification. However, there are no records documenting when this verification cycle was performed, what articles were (b) (4) in the load, or the lot number of the biological indicator challenged. In addition, the written procedures for verification of your (b) (4) cycle do not reflect current operations.

Observation 2: Sterility assurance parameters were not met due to your failure to adequately evaluate your (b) (4) define appropriate parameters for drug product sterilization, and maintain documentation of sterilization. For example, the following products require (b) (4) sterilization per your firm's formulary

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worksheets; however no records exist documenting their sterilization:

- Dexamethasone Acetate, Lot 20120222@3
- Testosterone Aqueous Suspension, Lot 20120515@3
- Triamcinolone Acetonide Injection 40mg/ml, Lot 20120530@1
- Ciprofloxacin/Dexamethasone Sterile Inj., Lot 20120726@9

Observation 3: Distribution of the Testosterone Aqueous Suspension 50mg/ml inj., Lot 20120515@3 occurred prior to receipt of final product test results. It was shipped on 5/23/12 and 6/21/12 from your firm, however preliminary results from your contract testing lab were not reported until 10/8/12.

Observation 4: Vials used in filling sterilized preparations have not been rendered free from viable microbes through the use of a validated (b) (4) [redacted] cycle. Management stated that such articles are (b) (4) [redacted] using the (b) (4) [redacted] cycle of their (b) (4) [redacted]. This cycle has not been challenged to ensure it is capable of achieving at least a 3-log reduction in endotoxin levels.

Observation 5: Records documenting the dates, load cycle, and lot number of vials washed and (b) (4) [redacted] are not been being maintained.

Observation 6: The current system for monitoring environmental conditions existing within the aseptic processing areas is deficient.

Specifically,
(a). Your procedure entitled, "3.060 Environmental Monitoring of the Aseptic Compounding Area: Microbial Organisms", dated 1/4/06, does not describe whether sampling is performed under dynamic conditions; described sampling locations do not correspond to the areas actually sampled; nor does the procedure describe what type of media should be used for incubating such samples.

(b). Personnel monitoring and environmental sampling is not performed and documented during aseptic processing. In addition, gloved fingertip monitoring is only being performed as part of (b)(4) [redacted] employee validations. Environmental sampling is performed (b) (4) [redacted]

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(c). EnviroTest Monitoring Logs dated 12/27/10-12/5/12 do not include inclusive incubation times, media type and expiration, or document the length of time settling plates were exposed to the environment.

(d). Neutralizing agents are not added to the media, to ensure that the growth potential of such media is not inhibited due to disinfectants applied to surfaces within the clean rooms.

(e). Media to support the growth of fungi (such as Malt Extract Agar) is not being used in high-risk level sterile preparations as part of your clean room environmental monitoring program.

(f). Nonsterile media is used to prepare solutions used in (b) (4) [redacted] media fills.

(g). Results of repeated microbial testing of environmental samples are not documented in instances were CFU counts >1 were found. For example, on 8/15/12, CFU counts of 4 were noted in the ante room, 14 counts were noted in outer room sink, and 15 counts were noted in the outer room floor. The comments denoted "clean and retest", however no additional results were recorded.

(h). Records documenting incubated personnel touch plates do not identify media lot used or incubation times.

(i). Full identification of microorganisms found within the ante room was not made in the following instance when environmental action limits were exceeded: On 8/25/12, Sample #4 (anteroom, ISO 7) showed 13 CFU microbial counts, where the action limit is >10cfu's. Section 5.2.8 of SOP, 3.060 Environmental Monitoring of the Aseptic Compounding Area, states that "any CFU's must be identified".

(j). (b) (4) [redacted] viable particle count reports provided by your contract testing company, (b) (4) [redacted] (b) (4) [redacted] do not indicate whether such testing is performed under dynamic conditions. Such reports are also not being reviewed, evaluated and approved by QA.

(k). The (b) (4) [redacted] continuous environmental monitoring software system has not been properly validated to ensure data is continuously captured and saved. For example, monitoring data requested for October 1-7 2012 could not be provided during the inspection. According to management, the system automatically overrides such data after (b) (4) [redacted] data points are collected.

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(l). Growth promotion testing is not performed on any purchased media used for environmental monitoring and sterility testing of products to ensure such media is capable of supporting growth.

(m). Media fills do not simulate routine aseptic manufacturing operations that incorporate worst case activities and conditions that may provide a challenge to your aseptic operations (such as; maximum batch sizes, maximum personnel, interventions, container/closure systems, etc). Currently, your media fills are only performed as part of employee (b) (4) [redacted] qualifications.

(n). No smoke studies have been conducted to verify the unidirectional airflow and air turbulences within clean room critical areas were sterilized drug products, containers, and closures are exposed to environmental conditions.

Observation 7: There is no documentation that supports the extension of the BUD dates outside of the duration of therapy. Your procedure entitled," Beyond-Use Dating (BUD)of Compounded Preparations", SOP 9.050, sec 9.4 states that," for all other formulations, a BUD is no later than the intended duration of therapy or 30 days, whichever is earlier". For example:

*Testosterone Aqueous Suspension, Lot # 20120515@3, BUD of 5/15/13;
* Zinc sulfate 1mg/ml injectable Lot # 20120319@ 12 made on 3/19/12 with BUD of 6/17/12;
* Clonidine/Bupivicaine/Baclofen Pf Intrathecal lot 20110315@4 made on 3/15/11 with BUD of 5/14/11.

Observation 8: Your firm cites USP <797> and USP <71> as their guidance for sterility and endotoxin testing requirements. As such, sufficient samples in relation to the formulation batch size are not routinely sent to your contract testing lab. For instance:

Glycopyrrolate 0.2mg/ml (5ml MDV); Lot no. 20121030@8 - (b) (4) [redacted] vials ; 2-5ml vials sent to lab;
Ketorolae Tromethamine 30mg/ml: Lot no. 20120113@4 - (b) (4) [redacted] vials ;3-1ml vials sent to lab:
Furosemide Inj. 10mg/ml; Lot no. 201220504@3- (b) (4) [redacted] vials; 3-1ml vials sent to lab;
Metoclopramide Inj 10mg/ml; Lot no. 20120912@6 - (b) (4) [redacted] units; 4-2ml vials

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In addition, there are no quality control procedures addressing the statistical criteria used to justify such sampling size.

Observation 9: Formulation worksheets are not sufficiently reviewed to ensure accurate and complete information is recorded. The following errors were consistently made without justification:
1. Lot number and expiration dates of chemicals are not recorded or incorrectly recorded;
2. Device lot numbers are not recorded for vials, stoppers, filters used;
3. Formulation instructions were incomplete;
4. Expired chemicals used in formulations, and use of chemicals due to expire prior to the Beyond-Use Date of the finished product.

Observation 10: (a).Your firm failed to thoroughly investigate the QREs (Quality Related Events) for Epinephrine 1:1000 PF Sulfite Free Injectable lots 20121018@9 and 20121024@8 and dispensed from 11/2-11/7/12 with reported pink discoloration, which resulted in the recall of both lots. No units were sent to the contract testing lab for further testing, nor investigation into previous lots were made to determine root cause and implement corrective actions to prevent reoccurrence.

(b).Sodium Bicarbonate 50 ml vial 8.4% inj., lot ~~2012115@5~~ 20121115@5 BSC 1/18/13 was found with visible particulate matter, and vials of such lot were bagged and labeled '[redacted] (b) (4)'. The formulation worksheet however does not denote the presence of particulates, and no additional investigations into the root cause of this quality problem were made. Continuous particulate matter has been noted in additional formulations without any laboratory evaluations.

Observation 11: There is no documentation of any investigations conducted for over 150 compounded preparations and raw materials that were identified as being "Out of Spec", "Not Pass QA", or "Rejected" on destruction logs dated 12/4-7/12.

Observation 12: There are no written procedures and documentation thereof addressing the subsequent stability, microbial and potency characteristics of stock solutions throughout their labeled Beyond-Use Date, from which multiple aliquots are withdrawn to prepare additional sterile formulations.

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