DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District 6th Ave. & Kipling St. - Bldg 20 DFC P.O. Box 25087 Denver, CO 80225-0087 Phone: (303) 236-3000 Industry Information: www.fda.gov/oc/industry	01/24-28/2011 & 02/01/2011 & 02/04/2011
	FEI NUMBER 1713747

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Steven D. Marler, Director of Operations, Ogden Manufacturing

FIRM NAME	STREET ADDRESS
Fresenius Medical Care, North America	475 West 13th Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ogden, Utah 84404	Sterile Drug Manufacturer

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:

1. The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

Procedure, (b) (4) states an action plan must be generated and referenced in the CAPA Report for any CAPA that has not been closed within (b) (4). This plan should identify what is to be done, by whom, and when it is to be completed and requires updates to be maintained.

1.A. CAPA (b) (4) was initiated on (b) (4). This CAPA is deficient in that:

Since (b) (4) no updates and/or designated responsibilities have been documented regarding the status of the critical change identified to (b) (4)

(b) (4) extensions lack sufficient justification and the CAPA remains open.

(b) (4) of the CAPA Report has not been completed to include any root cause analysis, corrective action, or preventative actions.

1.B. CAPA (b) (4) was initiated on (b) (4). This CAPA is deficient in that:

Since (b) (4) no updates and/or designated responsibilities have been documented regarding the status of the critical change identified to (b) (4)
(b) (4)

(b) (4) extensions lacking sufficient justification have been documented and the CAPA remains open.

(b) (4) of the CAPA Report has not been completed to include any root cause analysis, corrective action, or preventative actions.

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02/04/11

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1.C. There is no documented evidence to support that an effectiveness check has been performed since (b) (4) (b) (4) as required in CAPA (b) (4) The acceptance criteria associated with the CAPA is (b) (4) (b) (4)

In addition, the remaining Observations include evidence of inadequate or missing procedures and approval of deficient documents.

2. The firm performs stability sterility testing on the following drug products: (b) (4) (b) (4)

These SOPs are found inadequate in that they do not contain specific instructions and monitoring requirements to assure a complete data assessment in the event of a sterility failure investigation, for example:

2.A. SOP (b) (4) (b) (4) (b) (4) The procedure does not require the monitoring of all these locations and areas during each testing session.

2.B. SOP (b) (4) The procedure does not assure that monitoring is conducted when the sterility testing is completed.

2.C. SOP (b) (4) (b) (4) The procedure does not assure that fingertips are always monitored when the sterility testing is completed.

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2.D. SOP (b) (4) (b) (4) The procedure does not assure that critical areas within the testing location are always monitored when the testing is concluded.

2.E. SOP (b) (4) The procedure does not indicate (via wording or diagram) the (b) (4) (b) (4)

2.F. In addition, SOP (b) (4) is not specific, in that, there is no description of the steps performed to (b) (4) (b) (4)

3. Sterility testing performed as part of stability testing of (b) (4) is performed in a (b) (4) which has not been qualified as a (b) (4) (b) (4) area. The firm does not have procedures nor does the firm conduct non-viable particle concentration testing or microbiological active air testing in this (b) (4) In addition, smoke studies have not been performed to demonstrate the (b) (4)

4. (b) (4) stability sterility tests of (b) (4) were performed in (b) (4) (b) (4) when the (b) (4) (b) (4) an Instrument Status Change form, dated 0 (b) (4) states the (b) (4) and an Instrument Status Change form, dated (b) (4) (b) (4) states the "(b) (4) with the following comments, (b) (4) (b) (4) (b) (4) The associated Calibration Nonconformance Report (b) (4) contains a section titled, "(b) (4) which contains the following explanation: "(b) (4) There is no documentation of (b) (4) the use or results of environmental settling plates or a (b) (4) surface sample when the (b) (4) is used.

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FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

PURGED

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In addition, for the (b) (4) a Calibration Nonconformance Report (b) (4) was filled out due to: (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) The original out-of-tolerance test result for the (b) (4) (b) (4) however, there is no (b) (4) This calibration record was signed as verified on (b) (4) calibration was again performed, stating, (b) (4) (b) (4) The Calibration Nonconformance Report contains a section titled, (b) (4) which contains the following explanation: (b) (4) (b) (4) Again, there is no documentation of the use or results of environmental settling plates or a (b) (4) surface sample when the (b) (4) is used.

5. Drug products failing to meet established specifications are not rejected.

Specifically, your firm failed to provide adequate justification for the acceptance and release of (b) (4) (b) (4) which was confirmed for out of specifications (OOS) pertaining to the active ingredients (b) (4) For example:

5.A. Justification for release of this OOS product was based on stability data performed on product which had initially met specification as required by (b) (4)

5.B. Your firm re-worked this lot (b) (4) which is not in accordance with (b) (4) which states that (b) (4) (b) (4)

5.C. Finally, you failed to conduct analytical testing on the re-worked product to demonstrate that the lot met all finished product specifications prior to approval and distribution.

6. Test procedures relative to appropriate laboratory testing for sterility are deficiently written and not followed.

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Specifically,

6.A. Your firm failed to conduct sterility stability testing for (b) (4) finished products in accordance with your procedures (b) (4) (b) (4) Written procedure (b) (4) was also deficiently written in that not all test parameters were required to be recorded. For example, of the (b) (4) stability sterility test records reviewed (b) (4) the following deficiencies were noted:

6.A.1. For each of the (b) (4) there was no documentation of time, temperature, and incubator identification for sterility samples and controls;

6.A.2. For each of the (b) (4) there was no documentation of surface tests required by procedure (b) (4) (b) (4)

6.A.3. For each of the (b) (4) there was no documentation of settling plates required by procedure (b) (4) (b) (4)

6.A.4 (b) (4) tests selected (dated 2/2009 to 4/30/2010) utilized (b) (4) which was not tested (b) (4) (b) (4) which states that you follow U.S.P. Sterility Testing.

6.B. Your firm failed to prepare (b) (4) used for sterility stability testing in accordance with written procedure (b) (4) In addition, complete data is not recorded in the (b) (4) batch production records and the documents are not independently examined for accuracy. For example (b) (4) batch records reviewed were deficient in that:

(b) (4)

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(b) (4) [redacted]

7. SOP (b) (4) Validation Protocol, Quality, Sterile Room (b) (4) was utilized in association with Change Number (b) (4) s inadequate and Change Number (b) (4) was inappropriately approved as (b) (4) as evidenced by:

7.A. Change Number (b) (4) states, (b) (4) [redacted]

(b) (4) [redacted] Room testing for Change Number (b) (4) was performed on (b) (4) [redacted] none of these days were working days of testing.

7.B. (b) (4) [redacted] The procedure does not indicate which of the (b) (4) sites should be chosen for testing; in addition, the firm does not have any documentation to show which sites were chosen for sampling for Change Number (b) (4) [redacted]

The firm's practice is to place (b) (4) [redacted] however, this is not documented.

7.C. Change Number (b) (4) was approved on (b) (4) [redacted] issues were identified during the visual inspection and there is no documentation they were corrected. The visual inspection of Sterility Suite (b) (4) [redacted]

7.D. On 01/28/11, during the inspection of the stability sterility testing room (b) (4) the following

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unacceptable conditions were observed:

7.D.1. The junction between the flooring and the wall located below the observation window was found to have chipped paint along the edging (approximately six inches long);

7.D.2. The junction between superficial vinyl flooring segments, located in the center of (b) (4) was raised leaving a gap (approximately 2.5 inches in length) to the solid flooring beneath;

7.D.3. The wall immediately to the right of the observation window into (b) (4) as well as to the immediate left of the only door to the suite were observed to have protruding objects with no identified function; and,

7.D.4. The HEPA filters showed evidence of repair to the filter surface; however, there is no documentation supporting retesting of the HEPA filters after repair and prior to use.

8. The firm performs leak testing of the HEPA filters in the (b) (4) per the Original Equipment Manufacturers (OEM) procedure, (b) (4) (b) (4) The manual does not require a full scan of the entire filter face and frame. The manual states, (b) (4) In addition, although the firm performs repairs of leaks found in HEPA filters in the (b) (4) the firm does not have a procedure describing repairs or the requirement to retest after repair.

9. SOP (b) (4) Quality, Biological, Sterility Test, Sterile Suite Clothing Preparation and Gowning Procedure (b) (4) identifies the following dress requirements:

(b) (4)

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The procedure does not require personnel preparing (b) (4) and personnel conducting the sterility testing in (b) (4) to be completely gowned. In addition, the employee sanitizing (b) (4) including the (b) (4) was observed to don a plastic apron; however, there is no procedure describing the use of this article nor is the plastic apron sanitized or sterilized before use. The plastic apron is stored in the Sterility Suite Gowning Room/Anteroom outside of (b) (4)

10. SOP (b) (4) Quality, Biological, Sterility Test, Sanitization of Sterility Suite (b) (4) (b) (4) (b) (4) Quality, Biological, Preparation, Preparation of Bio Laboratory Supplies (b) (4) contains the instructions for preparing th (b) (4)

There is no requirement for the (b) (4) used in the sterility room and on the (b) (4) (b) (4) to be sterile. In addition, there is no requirement that sanitization materials used in (b) (4) including the (b) (4) are to be particle free. Currently, the firm uses towels and mops during sanitization and uses towels during testing; there is no documentation to support the towels and mops are particle free.

11. Analytical balances are used in the preparation of standards and are weight checked prior to use. However, the logbook containing standard preparations does not identify the balance used during the preparation. In addition, there are no limits established to determine if a balance is within tolerance when weight checks are performed. The identification of the standard weights used to perform weight checks is not documented. Logbooks of balance weight checks are not reviewed. In some instances, the unit of measure is not documented in the weight check logbook (b) (4)

12. (b) (4) solutions are (b) (4) tested by the firm per (b) (4) Prior to conducting the (b) (4) (b) (4) is performed on the (b) (4) and is recorded in a logbook. Although the log book is signed and dated as reviewed, there are no limits established to determine if the "Efficiency" and a (b) (4) are within tolerance by the performer or the reviewer.

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13. Written calibration procedures for analytical instruments are deficient in that they do not include specific directions, limits for accuracy and precision, and provisions for remedial action if limits are not met.

Specifically, your firm's test methods are deficient in that you failed to establish tolerance limits for check standards run on the (b) (4) laboratory equipment. Check standards were run on the (b) (4) prior to performing analysis on finished (b) (4) during this inspection. The (b) (4) check standards observed included:

(b) (4)

The accuracy and precision parameters which had originally been established in the validation of each test method, (b) (4) respectively, were never transferred to the method performed by the analysts and there is no documentation that the check standard data is reviewed prior to or after acceptance of the results.

14. The following Observations are in regards to the API (b) (4) The firm performed "Verification of the United States Pharmacopeia Calcium Acetate Monograph" under Engineering Test Report (b) (4) Review of the (b) (4) and associated data revealed:

14.A. Laboratory records do not contain documentation of the analytical balance(s) used for the analysis.

14.B. Water Test (b) (4) there is no documentation of the analyst performing the analysis, the lot number of the standard used for the analysis, and the date the analysis was performed. Although replicates of a (b) (4) standard were analyzed, acceptance criteria for the %RSD was not established prior to performing the analysis. (b) (4) was used as the standard (b) (4)

(b) (4)

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(b) (4) Per USP, Calcium Acetate is expected to have not more than 7.0% water and from the firm's analysis the Calcium Acetate tested (lot 1000019038) had a mean water test result of 5.23%.

14.C. Assay: there is no documentation of the analyst performing the analysis and the date the analysis was performed. Although replicates of a calcium carbonate standard were analyzed, acceptance criteria for the %RSD was not established prior to performing the analysis.

14.D. Lead Test (b) (4): there is no documentation of the analyst performing the analysis, the preparation or lot number of the standard used, and the date the analysis was performed.

14.E. Limit of Aluminum Test: there is no documentation of the preparation or lot number of the standard used.

14.F. Limit of (b) (4) there is documentation that the test was performed on (b) (4) however, the documentation of the preparation of the strontium standard states, (b) (4) and is dated (b) (4). There is no other documentation of another preparation of the ~~strontium~~ standard associated with this analysis.

14.G. The firm does not have a procedure for the receipt, identification, handling, and storage of laboratory samples, such as calcium acetate.

15. 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 already been distributed. Specifically, your procedure (b) (4) Product Complaint Handling Systems (b) (4)

(b) (4)

For complaints associated with (b) (4) the review of the (b) (4) did not extend to the manufacturing records for the subassembly of the bag fabrication for the associated lots. Examples include:

(b) (4)

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(b) (4) [redacted]

16. Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, your firm failed to identify and implement corrective actions in a timely manner which pertained to failed batches of (b) (4) [redacted] For example, (b) (4) [redacted] confirmed finished product batch failures selected for review (within the date range of 8/2009 to 9/2010) were identified with the root cause of production employee error. Each of the corresponding investigations referenced the corrective action plan (b) (4) [redacted] which targeted plant-wide reduction of operator error occurrences. This corrective action plan has been open since (b) (4) [redacted] and your firm has not yet implemented any plant-wide employee corrective actions or corrective actions pertaining to the production process including (b) (4) [redacted] The associated batches included:

(b) (4) [redacted]

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(b) (4) [redacted]

In addition, the SOP governing QIP's (Quality Improvement Projects) (b) (4) [redacted] does not include provisions for time frames, updates, and closures to ensure timely implementation of identified quality improvements.

17. Employees engaged in the manufacture of a drug product lack the training required to perform their assigned functions.

Specifically, employees performing sterility testing of stability samples for (b) (4) [redacted] (b) (4) [redacted] were observed to lack the training required to perform the aseptic operations for appropriate sterility testing in accordance with written procedure (b) (4) [redacted] (b) (4) [redacted] For example,

17.A. Your firm's (b) (4) [redacted] microbiological technicians who perform sterility testing were last trained on aseptic techniques during their initial hire training (b) (4) [redacted]

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SEE REVERSE OF THIS PAGE	Ginger Sykes	Investigator Ginger M. Sykes, Investigator Matthew R. Dionne, and Investigator Theressa B. Smith	02/04/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District 6th Ave. & Kipling St. - Bldg 20 DFC P.O. Box 25087 Denver, CO 80225-0087 Phone: (303) 236-3000 Industry Information: www.fda.gov/oc/industry	01/24-28/2011 & 02/01/2011 & 02/04/2011
	FEI NUMBER 1713747

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Steven D. Marler, Director of Operations, Ogden Manufacturing

FIRM NAME	STREET ADDRESS
Fresenius Medical Care, North America	475 West 13th Street
CITY, STATE AND ZIP CODE Ogden, Utah 84404	TYPE OF ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

17.B. The critical points identified in the demonstration video used for training aseptic processing of each employee are not applicable to the sterility testing processes performed by your firm;

17.C. On 1/26/11, we observed an employee performing aseptic operations during the (b) (4) (b) (4) testing of the (b) (4) This employee's aseptic operations were deficient in that:

17.C.1. Media surface enclosures were not maintained in the flow of HEPA filtered air during each filter insertion process;

17.C.2. Settling plates were not used as required by procedure (b) (4)

17.C.3. The tweezers used to remove the filters and place them into the media were allowed to sit in a (b) (4) (b) (4) which was not documented in any written procedure. The tweezers were then ~~dried by~~ (b) (4) the analyst used them to remove the bacterial filters during the process.

18. 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 failed to retrain employees in response to complaint (b) (4) (b) (4) Although the Training Report (b) (4) states the employees were to receive "procedural" training (in reference to SOP (b) (4) General Dress Requirements) and were to be evaluated through direct observation, there is no documentation to show these requirements were performed.

In addition, during the inspection of the operations on 01/24/11, employees within the production rooms were observed inappropriately gowned; the snaps of the gown near the neck were not fastened. (b) (4) Solution, General, Dress Requirements (b) (4) was not followed, which states, (b) (4) (b) (4)

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19. Your firm failed to follow procedure (b) (4) Drug Review, (b) (4) which requires the (b) (4) (b) (4) fails to provide any information regarding the validation of (b) (4) sterilization cycle (b) (4) Critical Change (b) (4) for the (b) (4) products, approved on (b) (4)

Furthermore, the information in reference to this validation was not submitted to the Corporate Regulatory Affairs for submission in the Annual Drug Report for NDA# 20-171 and NDA #18-1883 (December 1, 2009 – November 30, 2010).

20. Procedure (b) (4) Systems, Drug Annual Report (b) (4) requires that documentation regarding information for the Drug Annual Report submission in reference to NDA #18-883 and NDA #20-171 be submitted to Corporate Regulatory Affairs by (b) (4)

The procedure fails to require your firm to maintain documentation that demonstrates all required information was submitted as required. There is no evidence to show that information in reference to NDA # 18-883 and NDA #20-171 for the reporting period (b) (4) was forwarded. This report has yet to be submitted to the approving office within FDA.

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