DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	01/24/2013 - 03/04/2013* FEI NUMBER 1950222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stephen C. Natsch, Vice President and General Manager

FIRM NAME	STREET ADDRESS
Meridian Medical Technologies a Pfizer Company	2555 Hermelin Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brentwood, MO 63144-2504	Human 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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

As a result of a Field Alert on Diazepam Autoinjector (NDA 20-124) your documented investigation of Out-Of-Specification (OOS) results for 3-Amino-6chloro-1-methyl-4-phenylcarbostyril (Carbostyril, one of the known degradants of Diazepam auto-injection product) a (b) (4)-month stability test interval ((b) (4) °C / (b) (4) %RH) for lots 8D1151 and RP-542-2S, and a (b) (4) month stability failure for lot no. 8D1082, was not extended to include associated lots. The investigation was not thoroughly conducted to detect the root cause (QAR # 12-05-001-SL) in that:

1. The investigation did not include any Diazepam API testing for impurity.

2. The investigation did not include a documented investigation of retained samples testing for Diazepam lots which were produced in 2009, 2010, 2011 and 2012.

3. The investigation found that Acetaldehydes were formed during (b) (4) month shelf life. No further investigation has been done.

4. Management stated that "Raw material (b) (4) is highly likely responsible of Carbostyril degradation". Therefore raw material (b) (4) specifications test method was changed on 8/30/2012 (SOP-LAB-RDL-00126-SL). No scientific data was provided to support this claim.

In addition:

5. Your investigation failed to include an inspection of your raw material supplier manufacturer for (b) (4) in lieu of your findings that this material was the "cause" for these failures.
Also, you have failed to conduct inspections of the following raw material suppliers who provide ingredients used to manufacture your human drug products in accordance to your SOP QLA-COM-00010 "Supplier Audit Procedure" and/or

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	Michele Perry -Williams, Investigator Amir A. Abdalla, Investigator Kathleen B. Swat, Investigator	03/04/2013

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review audit information from your "sources" to access their findings in relation to processing operations at this site. Your current SOP requires you inspect these excipient manufacturing sites every (b) years.

Product	Raw Material
EpiPen	Sodium Chloride USP (b) (4) (b) (4) KG
EpiPen	Sodium Meta-Bisulfite (b) (4) KG
ATNNA	(b) (4)
ATNNA	Phenol (b) (4) USP (b) (4) KG
ATNAA	Glycerin (b) (4) USP (b) (4) (b) (4) L
Diazapem	(b) (4) (b) (4) KG

5. Review of your raw materials supplier qualification documentation found you have failed to inspect your Phenol raw material supplier, used in the manufacture of ATNAA. Both Catechols and Bisphenyl Ethers are known degradants of Phenol. Subsequently, there was a Field Alert for ATNAA Injector, NDA 21-175, initiated 2/13/13, for a stability failure at the (b) (4) month time point for Total Known Impurities ((b) (4) (b) (4)

6. On (b) (4) during packaging accountability, Atropen Lot 2PF298 had overage of (b) (4) injectors equaling an unaccounted for variance of (b) (4)%. The acceptable established variance is (b) (4)%. Event Report 12-11-014-SL was generated and the lot was released based on the corrective and preventative actions outlined including changing the acceptable variance to (b) (4)%, initiated through change order 12BR31244. Change Order 12BR31244 makes no mention of a change in variance. Lot 2PF298 was released on (b) (4) and distributed on (b) (4) and (b) (4)

7. On (b) (4) foreign material was found on two needle/ferrell assemblies during filling operations for Atropen lot # 2MP470 which was sent to an outside testing lab for evaluation and review. You failed to conduct a thorough review of the outside testing laboratory's results dated (b) (4) which were not identified until 9/21/12, when you were requesting product be released to your customer through an FDA review. In addition, you have failed to inspect (i.e. never inspected) your contract testing laboratory used to perform this analysis in accordance with your SOP QLA-COM-00010-SL, "Supplier Audit Procedure". This SOP requires you inspect your contract testing laboratories every (b) (4) years.

OBSERVATION 2

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

Specifically,

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1. Your employees failed to follow your SOP -PRO-FIL-00002-SL, "Aseptic Processing Area Gowning" which instructs" employees should sanitize hands and arms (b) (4) times and then sanitizes hands only prior to gowning". On 1/29/13, nine out of (b) (4) employees sanitized hands and arms one time. None of the employees performed the (b) (4) sanitizations outlined in the protocol.

2. Per SOP-PRO-FIL-00002-SL, "prior to entering a Class 100 area, employees should change (b) (4) pair of gloves. Gloves should be changed immediately prior to entering the Class 100 area. Ensure that nothing is touched with the newly gloved hands". Class 100 rooms (b) (4) are designed with doors which open out into the hallway requiring employees to pull door handles in order to enter. Room (b) (4) is used for Diazepam and Atropine filling.

3. Media fill simulations of your sterile processing operations failed to include simulations of your worst case manufacturing operations. While you include examples of each of your interventions, you have failed to identify and mimic the number of each of these interventions which occur during your "worst case" manufacturing operations for the sterile injectable human drug products manufactured at your facility.

   For example, on (b) (4), we observed filling operations for Atropine Injectable, lot # 3PT123, filled in Suite (b) (4) From (b) (4) to (b) (4), we observed fourteen (14) interventions, seven (7) times when employees entered/exited the Class 100 area using their hands on the curtains, two (2) employees talking and an employee standing in the curtain with half of their body inside the Class 100 area for approximately 15 seconds.

4. You failed to include fluorescent light fixtures which hang down at least 3 inches from the ceiling over the sterile filling lines, Class 100 area, into your sanitization/cleaning program procedures, SOP-PRO-FIL-00047-SL, "Cleaning and Sanitizing of Aseptic Processing Areas". These light fixtures are located directly above the filling lines in at least three of your sterile filling suites (Rooms (b) (4) where EpiPen, Atropine, Combo-Pen and Diazapam are filled respectively). Impact of these light fixtures has not been assessed or established.

   In your Epi-Pen filling suite, Room (b) (4) you continue to have repeated Excursion Reports generated because of high particles observed during filling operations. You have failed to establish a root cause and initiate effective corrective actions for these particles which have alert/action limit of (b) (4) for (b) (4) um particles; and an alert limit of (b) for particles which are (b) (4) um.

   Specifically, between 1/6/12 and 8/1/12 you had the following Quality Assurance Reports (QAR) and Exception Reports (ER) generated for these excursions: QAR-12-01-001, dated (b) (4); QAR 12-04-004, dated (b) (4); NOE (Notice of Event/Deviation Report) 12-06-007, dated (b) (4) ER 12-07-006 dated (b) (4) and ER 12-08-002 (b) (4)

   For example:
   QAR-12-01-001, initiated (b) (4) for EpiPen, lot numbers 1GH811 and 2GH002, had excursions for high (b) (4) um and (b) (4) um particles observed during filling operations on (b) (4) EpiPen, Lot no. 1GH811 had 914 (b) (4) m) and 31

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(b) (4) um) particles. (b) (4) EpiPen, lot no. 2GH002 had particle excursions of 204 ((b) (4) um) particles and 6 ((b) (4) um) particles.

5. On 1/30/12, we observed cleaning operations in Suite (b) (4) and saw you do not always use an overlapping cleaning technique and you do not clean from the (b) (4) of your processing equipment (b) (4) and/or from the (b) (4) of the equipment (b) (4) in accordance with your SOP no. PRO-FIL-00047-SL "Cleaning and Sanitizing of Aseptic Processing Areas (APA)".

OBSERVATION 3

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

Specifically,

1. Material Reconciliation is not accurately recorded in Diazepam batch records for lots 2D2698, 2D2699, 2D2700 and 2D1743. Batch records, rework plans and results of rework do not reconcile.

a. On (b) (4) QAR-12-10-003-SL was initiated for Diazepam 2D2698 when 3 interior boxes were found without labels and 1 extra injector unit in a box was found after production on (b) (4), during the inspection process. A rework was performed without approval of Quality Assurance which found 2 interior boxes missing labels and one interior box was found to be missing 1 injector unit. The material reconciliation report for Diazepam 2D2698 documents an overage of 4 interior boxes, 2 exterior boxes, 4 instructions for use, 30 product inserts, and 1 interior box label. Additionally, the Inspection accountability log indicates zero unaccounted for injectors which does not reflect the overage of the one injector found in the box. The discrepancy could not be explained by Packaging, Product and QA Management.

b. On (b) (4) Lot 2D2699, the lot following 2D2698, was reworked when an overage of 2 packs of product inserts (15 each) were found during accountability. Rework found 12 of the interior boxes were found to have missing or incorrect contents. The batch record prior to rework indicates an overage of 12 interior boxes, 1 exterior box, 1 instruction for use card, and 30 product inserts. After rework, an additional material reconciliation report was generated and documents 6 interior box labels were issued, 2 were used, 1 held for sampling, and 3 rejected. Notes in this batch record document "1 interior box label was found missing on 1 interior box. 2 product inserts and 1 instruction for use cards were removed from rejected portion of lot to back fill boxes". Additionally for this lot, the packaging accountability does not reconcile. The discrepancy could not be explained by Packaging, Product and QA Management.

c. On (b) (4) Lot 2D2700, the next consecutive Diazepam lot, was reworked when the accountability was over 4 injectors, 30 product inserts, and 2 interior labels. Rework found 1 pack of missing product inserts, 2 interior labels,

and 3 injectors. The batch record documents an overage of 8 interior boxes, 1 exterior box, 5 instructions for use cards, and 15 product inserts. The packaging accountability record documents an overage of 1 injector and is without any changes. The discrepancy could not be explained by Packaging, Product and QA Management.

d. On (b) (4), Diazepam Lot 2D1743, there were 3 unaccounted for labels after packaging. A 100% inspection was conducted without approval of Quality Assurance and one box was found without a label. On (b) (4) the label was applied and the lot was released. The material reconciliation report documents an overage of 2 interior box labels on (b) (4) There are no changes to the batch record. The discrepancy could not be explained by Packaging, Product and QA Management.

2. Rework was conducted on Diazepam lot numbers 2D2698, 2D2699, 2D2700, and 2D1743 even though the material discrepancy was within your acceptable established variances without documented justification.

3. You have failed to use the appropriate sampling plan (i.e. ANSI/ASQ A1.4-2008, Level II, Single Sampling Plan) specified in your Master Batch Records for the secondary and tertiary packaging containers used to package sterile injectable products manufactured and packaged at your facility.

4. On (b) (4), (b) (4) samples of (b) (4) each were removed from (b) (4) lots of ATNAA (lot numbers (b) (4) (b) (4) which were not recorded in the packaging record.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

1. Inventory Control System is not reliable or accurate:

Specifically,

a. EpiPen lots 2GH343, 2GH400, and 2GH305 were observed in the corner of the SPS Warehouse on 1/24/13 in red quarantine bags on shelves above an air compressor. Upon inquiry, it was determined Lot 2GH343, consisting of (b) (4) units was given a quarantine notification on 7/17/12, Lot 2GH400, consisting of (b) (4) units was given a quarantine notification on 8/9/12, and Lot 2GH305, consisting of (b) (4) units was given a quarantine notification on 6/5/12. All three lots were quarantined due to high particle counts. Although the lots were physically quarantined, they were not quarantined in the (b) (4) inventory system by Quality Control. The quarantine notifications were not signed and dated by Quality Control. Upon return to the SPS warehouse on 1/28/13, the three quarantined EpiPen lots had been disposed into blue reject containers.

b. ComboPen lot 2TF619 was observed in the corner of the SPS Warehouse on 1/24/13 in red quarantine bags on

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shelves above an air compressor. Upon inquiry, it was determined Lot 2TF619, consisting of (b) (4) units was rejected due to high particulates on (b) (4). Lot 2TF619 was physically moved from the SPS Warehouse to Westport on 1/25/13. On 1/28/13, the warehouse supervisor electronically moved Lot 2TF619 in the (b) (4) inventory system from the SPS Warehouse to Westport and backdated it to reflect a transfer on 1/26/13. The Warehouse Supervisor stated this is common practice at the end of the month because the system locks out.

c. Specifically, (b) (4) units of EpiPen Lot 2GH400 were removed from inventory to reconcile paperwork by warehouse personnel without authorization by the quality unit. Unbeknown to the warehouse, the units were being held in a quarantine status in the production facility.

2. You failed to follow your SOP no. SOP-MAN-GEN-00084-SL "Uniform Requirements For Westport Testing/Sampling And Manufacturing Areas" at your "Base" facility which is used to assemble, and label/package Morphine Injectable product as these items were not seen at this location: Beard nets, safety glasses, gloves, steel toe shoes or shoe covers, Tyvek gowns or company issued garments stored and used by the employees and/or visitors during our review of this area.

OBSERVATION 5

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically, you failed to timely communicate and report information regarding a Field Alert for ATNAA Injector, NDA # 21-175, lot no. 9M1050, for a stability failure at (b) (4) months for the Total Known Impurities (b) (4) (b) (4)

The Analyst and second reviewer failed to recognize the failing results on 1/30/2013 and 2/6/2013 respectively, with the Field Alert being reported on 2/13/2013. Additionally, there were no initials or signature of a second person showing the test had been reviewed for accuracy and completeness for (b) (4) Analysis ((b) (4) book #3 page 25 of 150). This was performed on 1/11/2013 for ATNAA lot # 9M1050 stability testing at (b) (4) m (b) (4)° C.

OBSERVATION 6

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, your Quality Unit is deficient when changes are made and/or needed for your Master Production Records.

1. Obsolete Master Batch Record (Clean and Prep) was used for over (b) (4) batches of EpiPen from 3/13/12 through 7/20/12. In addition, when the new Master Record for Clean and Prep was created, the Quality Unit failed to verify the record to be replaced was obsolete so that the new version would be the correct version available for use during your "clean and prep" manufacturing operations for your EpiPen Injectable Drug Product.

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2. QA failed to monitor and verify changes initiated in Performance Qualification QP 11-117 "(b) (4) Filling Machines" dated 4/18/12 were completed. You failed to include changes made during this qualification to include Combo-Pen manufacturing operations and the need to change the (b) (4) from (b) (4) to (b) (4) prior to processing operations for Combo-Pen lot no. 2TF619, which started filling on (b) (4) You also failed to verify if this change had a negative impact on manufacturing operations for this product through appropriate qualification activities.

   Additionally, you didn't initiate change control documentation for this (b) (4) until 10/24/12 under VCC (Validation Change Control) 12-085, which was not monitored and completed according to your SOP QLA-VAL-00015-SL "Validation Change Control".

3. You failed to verify appropriate changes were made to the (b) (4) Master Record (Clean and Prep (b) (4) record) which includes information on the (b) (4) used during equipment sterilization runs. After the (b) (4) (b) (4) was removed from service (b) (4) the (b) (4) Master Batch records were not updated to remove the reference to the load configuration (b) (4) on the Master Batch Records for the clean and prep (b) (4) stage of the processing operations.

4. The Quality Unit failed to make changes to your Packaging Master Batch Record for (b) (4) after the customer changed their logo which resulted in the need to change the (b) (4) carton pharmacode from "(b) (4)" to "(b) (4).

   You also failed to initiate change control after the printed material specification for this carton pharmacode was effective on 3/12/12 until 1/22/13 which was initiated under Change Order no. 13BR22166.

OBSERVATION 7

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy and completeness.

Specifically,
There are no initials or signature of a second person showing that the following tests have been reviewed in the laboratory notebooks:

1) Morphine Assay by (b) (4) was performed on 4/11/2012 (Morphine book #1, page 23 of 100). Management stated that there was no record found related to this test.
2) Moisture determination by (b) (4) was performed on 4/12/2012 ((b) (4) Book # 9, page 5 of 100) used for Atropen in house standards requalification ((b) (4) .
3) Morphine Assay for Morphine ((b) (4) lot # 2HD580, basic unit production was performed on (b) (4) (Notebook BB

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19, page 16).

4) (b) (4) test for EpiPen lot # RP609-2, stability testing at (b) (4) month/(b) (4)°C was performed on 12/19/12 (Notebook BB 19, page 26).

5) (b) (4) test for Diazepam stability testing for lot # (RP659-1S (b) m/(b) (4)C, RP659-2S (b) (4) n/(b) (4)°C, RP659-3S (b) m/(b) (4)°C, RP659-1S (b) m(b) (4)C, RP659-2S (b) m/(b) (4)C, RP659-3S (b) m/(b) (4)C). The test was performed on 12/20/12 (Notebook BB 19).

6) (b) (4) analysis (b) (4) book #3, page 25 of 150), was performed on 1/11/2013 for the following lots:

ATNAA lot # 9M1050 stability testing at (b) (4) m/(b) (4)C

Pediatric Atropine lot # 2PF769 release testing

Atropen lot # 2PF770 release testing

ATNAA lot # 1M1015 stability testing at (b) (4) m/(b) (4)°C

ATOX lot # 2AM774 release testing

In the Production/Processing areas, there are no initials/signature, or the approving signature is ineffective as there are omissions that were not detected by the final reviewer for the following:

1. (b) (4) dose, lot # (b) (4), during Sterilization Run no. (b) (4) on 7/25/12, there was no verification signature on steps no. 1 and 2, but was signed and dated by the Supervisor on 7/25/12 on the clean and prep record, section Equipment Preparation - EAM (Equipment Automated Machine) Machine Prep/Sterilization Section.

2. EpiPen Jr, Lot # 2GK608, during compounding (i.e. formulation) operations on (b) (4) step (b) (4) the verification signature for cleaning per SOP PRO-GEN-00006 is not documented; and step (b) (4) the tasks referenced here is signed as performed by and verified by, however, the results for this step (b) (4) is not recorded.

OBSERVATION 8

Records are not kept for the maintenance of equipment.

Specifically, you failed to document each preventive maintenance (PM) task individually performed on over (b) (4) valves located on your (b) (4) Systems (b) (4) and over (b) (4) valves located on your (b) (4) System (b) (4) In addition, your SOPs #'s MNT-PRM-00179 and MNT-PRM-00176 titled "Operation and Maintenance of the (b) (4) System (b) (4) and "Operation and Maintenance of the (b) (4) System (b) (4) respectively, fail to instruct the technicians to record this information for each PM task performed. Your (b) (4) produced in these systems is used during manufacturing operations of your sterile injectable drug products.

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OBSERVATION 9

Buildings used in the manufacturing, processing, and packing of a drug product are not maintained in a good state of repair.

Specifically,

1. At your "Base" facility used for Morphine Injectable assembly, labeling and packaging operations, the facility is not maintained in a clean and good state of repair. We observed at least 8 holes in the ceiling tile, at least 4 water spots in the ceiling tile, obvious dust on the ledges in the Morphine assembly Room no. (b) (4) and obvious dirt on the floors of the warehouse and Morphine assembly Room no. (b) (4)
   Additionally, your cleaning record documentation for your Assembly Room no. (b) (4) and warehousing areas used to assemble your Morphine Drug units, along with finished packaging and labeling was not reviewed and approved after tasks were performed from the week of 1/7/2013 through 1/17/2013.

2. We observed rust on a pipe in your formulation suite (Room (b) (4) used to compound all of your sterile injectable products.

*** DATES OF INSPECTION:**
01/24/2013(Thu), 01/25/2013(Fri), 01/28/2013(Mon), 01/29/2013(Tue), 01/30/2013(Wed), 01/31/2013(Thu), 02/01/2013(Fri), 02/04/2013(Mon), 02/05/2013(Tue), 02/06/2013(Wed), 02/08/2013(Fri), 02/11/2013(Mon), 02/12/2013(Tue), 02/13/2013(Wed), 02/14/2013(Thu), 02/15/2013(Fri), 02/19/2013(Tue), 02/20/2013(Wed), 02/25/2013(Mon), 03/01/2013(Fri), 03/04/2013(Mon)

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