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	02/23/2009 - 04/21/2009* FEI NUMBER 1000118231

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ronald A. Schultz, Sr. Vice President of Quality Management, North America

FIRM NAME	STREET ADDRESS
TEVA Animal Health Inc	3915 S 48th St Terr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Joseph, MO 64503	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:

Observations cover inspections at the following firms inspected from 2/23/09 to 4/21/09:

Teva Animal Health, Inc., 3915 S 48th St Terr, St. Joseph, MO 64503 -FEI #1000118231
Teva Animal Health, Inc., 5915 Corporate Drive, St. Joseph, MO 64507 -FEI #3002928254
Teva Animal Health, Inc., 5909 Corporate Drive, St. Joseph, MO 64507 -FEI #3003363010
Teva Animal Health, Inc., 5920 Corporate Drive. St. Joseph, MO 64507 -FEI #3003569629
Teva Animal Health, Inc., 4621 Easton Road, St. Joseph, MO 64503 (No FEI/CFN).

OBSERVATIONS 1-9 ARE CONCERNING THE QUALITY SYSTEM

OBSERVATION 1

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

Specifically,

The Quality Unit has failed in their responsibility and authority to monitor and implement Quality Systems. This failure is evidenced by observations 2-17.

FAILURE OF THE FIRM'S QUALITY CONTROL/QUALITY ASSURANCE FUNCTIONS IS A REPEAT DEFICIENCY FROM THE PREVIOUS INSPECTION.

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Eric M. Mueller, Investigator Ralph H. Vocque, Chemist Danial S. Hutchison, Investigator Patrick L. Wisor, Investigator Warren J. Lopicka, Investigator	04/21/2009

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OBSERVATION 2

Drug products failing to meet established standards, specifications, and quality control criteria are not rejected.

Specifically,

A) Your firm failed to reject the entire lot of Thiamine HCL 200 mg Injection, lot 7060828, which was found to contain particles on or about 1/8/09. This product was released to the market on 10/24/07.

B) Your firm failed to reject eight lots of Levothyroxine 0.5 mg tablets, which failed to meet specifications. An FDA review on 3/26/09 of the retain samples found tablets which failed the appearance specification of an intact white tablet (0.5mg). Tablets were found with "capping" and a variety of unexplained spots which fail the white tablet appearance specification. Lots with these defects include: 7101397, 7030466, 6071146, 7111484, 7111485, 8020130, 8020129, and 6091479. These lots were released to market between 8/22/06 and 3/24/08.

Additionally, your firm failed to reject seven lots of Levothyroxine 0.8 mg tablets which failed to meet specifications. An FDA review on 3/26/09 of the retain samples found tablets which failed the appearance specification of an intact blue tablet. Tablets were found with "capping", "picking", and a variety of unexplained spots which fail the blue tablet appearance specification. One tablet was found which was disintegrating. Lots with these defects include: 7040662, 8020133, 8030221, 8010043, 7101400, 7111487, and 7111486. These lots were released to market between 9/6/07 and 4/10/08.

Additionally, your firm failed to reject lot 7071016 of Levothyroxine 0.2 mg tablets which failed to meet specifications. This lot was released to market on 9/5/07. An FDA review on 3/26/09 of the retain sample found tablets which failed the appearance specification of an intact Pink tablet. Three tablets were found "capping", 2 were cracked and 1 was broken.

C) There have been (b) (4) lots of Praziquantel Injection, ANADA 200-176, released since 2006 with an unapproved specification. As of February 1, 2006, the specification approved in the application was "clear, colorless to tinted". Lot 7060853 failed the stability specification on 9/19/07 because it was pink

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and was released to market 10/24/07.

OBSERVATION 3

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Small Volume Parenterals (SVP):

A) The firm's investigation, completed on 2/9/09, into Thiamine HCL Injection 200 mg Lot 7060828, released to market 10/24/07 regarding foreign material floating in the product, did not extend to other drug products that may have been associated with this problem. It is also deficient for the following reasons:

1) An outside firm analyzed samples from this lot and noted that particles were (b) (4) complexed with either Thiamine HCL, (b) (4) or its derivatives. No documentation in the investigation exists to show the firm reviewed other lots of this product or other lots of product potentially affected by this problem.

2) The firm did not conduct a review of their manufacturing equipment which may have caused (b) (4) (b) (4) in their product.

3) Deviation Report DR # (b) (4) reads "Cause of Deviation: Process", yet there is no documentation in the investigation explaining what portion of the "Process" caused the deviation.

4) Deviation Report (b) (4) does not take into account the safety or efficacy risks associated with (b) (4) (b) (4) or its derivatives that were identified in this lot of product.

Additionally, the risk assessment concerning efficacy and safety of this product was not made by a person qualified to make this determination (Doctor of Veterinary Medicine or equivalent clinical personnel).

5) Effective corrective and preventative actions were not taken to ensure the problem of thiamine/ (b) (4) complexes does not occur in the future.

Large Volume Parenteral (LVP):

B) The firm's deviation investigation and report for OOS results regarding high particulate counts for Sterile WFI, USP, Lots 809110F released to market 12/8/08, 809123F released to market 12/5/08, 810124F released to market 12/8/08, (b) (4) not yet released to market, and 8100727 released to market 1/15/09, did not extend to other batches of product manufactured that may have been associated with this problem.

1) Sterile WFI, USP, Lots 809110F, 809123F, 810124F, (b) (4), 8100727 failed in house particulate testing, but only lot 810124F was sent to an outside laboratory for identification/confirmation. The summary is incorrect in that it reads in part "Samples of the affected products were sent to *** for positive identification/confirmation of the particulate material suspected to be (b) (4). *** did confirm the material to be (b) (4) "

2) The firm failed to address possible sources of contamination identified by an outside laboratory for Sterile WFI, USP, lot 810124F.

IT IS IMPORTANT TO NOTE THAT THE WATER FOR INJECTION IS USED FOR CLEANING, VIAL WASHING, AND IS AN INGREDIENT IN EVERY PRODUCT PRODUCED IN THE (b) (4) FACILITY.

TABLETS:

C) The complaint investigation into complaint 08-114, received 6/10/08, for crumbling Levothyroxine 0.5 mg tablets, lot 7101397 released to market 11/30/07, failed to extend to other lots of the same product which had also received similar complaints. By the time this complaint was received, lots 6091489 released to market 10/9/06, 6091479 released to market 11/27/06, 6071144 released to market 8/22/06 and 6091485 released to market 9/28/06, had already received similar complaints. It was not until the firm had received (b) (4) complaints, between 12/18/07 and 8/12/08, before a decision was made on or about 8/19/08 to conduct a comprehensive investigation. Complaints have been received for 0.5 mg,

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0.2 mg, and 0.8 mg tablets of Levothyroxine.

Additionally, the QA investigation failed to detect out-of-specification (OOS) tablets. On 3/26/09, FDA observed a QA review of retain sample tablets. Their review failed to identify tablets with defects including overweight and various unexplained spots in the following lots: 7101397, 7030466, 6071146, 7111484, 7111485, 8020130, 3/24/08, 8020129, 6091479, 7040662, 8020133, 8030221, 8010043, 7101400, 7111487, 7111486, and 7071016. These lots were distributed between 8/22/06 and 4/10/08.

FAILURE INVESTIGATIONS NOT EXTENDING TO OTHER LOTS OF PRODUCT POTENTIALLY AFFECTED BY THE PROBLEM IS A REPEAT DEFICIENCY FROM THE PREVIOUS INSPECTION.

OBSERVATION 4

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

A) The firm has failed to conduct Process Validation for the following Products:

Small Volume Parenteral:	Large Volume Parenteral:	Oral Solution:
Lidocaine 2% Injection	Cal-Phos #2 Injection	Amcalcilyte
Vitamin C Injection		Gluco-Amino-Forte
Vitamin B12 1000 Injection		Amino Acid
Vitamin B12 3000 Injection		Amino Acid Oral Concentrate
Vitamin B12 5000 Injection		
Thiamine HCL 200mg Injection		
Guaifenesin Injection		
Vitamin K1 injection 10 mg/mL		
D-Panthenol Injection		
Potassium Chloride Concentrate Injection		

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EMPLOYEE(S) SIGNATURE

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Ralph H. Vocque, Chemist
Danial S. Hutchison, Investigator
Patrick L. Wisor, Investigator
Warren J. Lopicka, Investigator

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Atropine Sulfate Injection
Epinephrine Injection 1:1000
P-Bloc (Sterile Pitcher Plant Extract) Injection
Mannitol Injection 20%

B) The firm's validation summary for Process Validation for the Manufacturing and Filling of (b) (4) (b) (4) (b) (4) Units per mL, ((b) (4)) dated 4/10/95, does not match the current manufacturing and filling process in the following respects:

1) The batch size of the lots used in the validation effort is (b) (4) Liters. Currently, the firm manufactures batch sizes of (b) (4) Liters for this product.

2) The fill time for the batches in the validation effort occurred over roughly (b) (4) hours. Currently, the firm is filling a batch of (b) (4) over a time period of roughly (b) (4) hours.

3) The equipment used in the validation effort, dated 4/10/95, is not the same as currently used to manufacture the product. For example, tanks, filter houses, bottle washer, stopper washer, autoclave, "sub" tanks, stopper and capping equipment are different than those currently used by the firm.

4) The (b) (4) validation effort and report was completed by a previous company. This validation effort was never reviewed by any person in your Validation Department or Quality Assurance Unit prior to this FDA inspection.

C) Your firm has no IQ/OQ documentation for more than (b) (4) pieces of critical manufacturing equipment used by the firm to manufacture drug products in the LVP and Solid Dose manufacturing areas.

D) No qualification and validation studies were performed on the (b) (4) equipment, property number (b) (4). No installation qualification (IQ) or operational qualification (OQ) for the (b) (4) system was performed. This equipment is used to determine particulate matter for both the (b) (4)s and (b) (4)'s. The IQ and OQ were not conducted on (b) (4) other primary pieces of TEVA's lab equipment, such as HPLC and GC systems. The HPLC and GC instrumentation is used for analysis of TEVA's products.

E) The firm failed to follow standard operating procedures in regards to validation. For Example:

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1) General Process Validation, S.O.P. (b) (4), was not followed. This procedure requires processes used in product manufacture to be validated. The following products do not have validated processes:

Small Volume Parenteral:	**Large Volume Parenteral:**	**Oral Solution:**
Lidocaine 2% Injection	Cal-Phos #2 Injection	Amcalcilyte
Vitamin C Injection		Gluco-Amino-Forte
Vitamin B12 1000 Injection		Amino Acid
Vitamin B12 3000 Injection		Amino Acid Oral Concentrate
Vitamin B12 5000 Injection		
Thiamine HCL 200mg Injection		
Guaifenesin Injection		
Vitamin K1 injection 10 mg/mL		
D-Panthenol Injection		
Potassium Chloride Concentrate Injection		
Atropine Sulfate Injection		
Epinephrine Injection 1:1000		
P-Bloc (Sterile Pitcher Plant Extract) Injection		
Mannitol Injection 20%		

2) Procedure (b) (4), "General Validation Policy" was not followed by the firm regarding the Qualification of Manufacturing Equipment in the LVP, Solid Dose and Oral Solutions area.

a) A review of manufacturing equipment was not performed by the firm prior to this inspection. A review conducted of manufacturing equipment during this inspection revealed deviations in qualification of manufacturing equipment used to manufacture drug products at this firm.

b) The firm has failed to evaluate the necessity of revalidation of the "PROCESS VALIDATION for the MANUFACTURE and FILLING of (b) (4) (b) (4) ((b) (4) UNITS per mL)" report dated 4/10/95. Since this validation effort by the firm, there have been changes such as (b) (4) batch size, (b) (4) fill time and different (b) (4) equipment.

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OBSERVATION 5

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

A) The procedure "(b) (4) Investigation and Reporting of Incidents and Deviations" was not followed. For Example:

1) Deviation Report # (b) (4) was initiated because of foreign material floating in the product Thiamine. The firm's Quality Assurance did not document the following requirements from the procedure:

a) Identify the cause of the deviation and final conclusion based on the investigation conducted and information collected. No cause of the deviation was documented or justified in this deviation report.

b) Outline corrective actions necessary to prevent similar occurrence of the deviation, including justification and documentation.

2) Deviation Report DR# (b) (4) was initiated to investigate OOS results for particulates in Sterile WFI, USP, lots: 809110F released to market 12/8/08, 809123F released to market 12/5/08, 810124F released to market 12/8/08, (b) (4) not yet released to market, and 8100727 released to market 1/15/09. The following was not followed or completed by QA as required procedurally:

a) Examine other batches of product manufactured before/after using the same equipment or by the same employee.

b) Consider how the deviation affects the disposition of the batch from the Regulatory, Compliance, Validation, Stability and Quality Aspects.

B) The Procedure for issuing an NADA/ ANADA Field Alert Report was not followed. Procedure (b) (4)-(b) (4) "Records and Reports, Use of Form FDA 1932" requires reporting to the FDA District Office within

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three working days of first becoming aware of information pertaining to product and manufacturing defects that may result in serious adverse drug events. This was not performed. For example:

1) A Field Alert report was not filed within three days for Thiamine 250 mL, lot 7060828 released to market 10/24/07, which contained particulate matter. The OOS was discovered on 1/8/09. The form used to report this Field Alert to FDA reads "Date Report Received 1/12/09" and it was not reported to FDA until "1/15/08". The 1/12/09 date would have met the three business day requirement, however no justification could be provided for the use of this date.

Additionally, the FDA form 1932 was filled out incorrectly in that the year of 1/15/08 recorded as "DATE SENT TO FDA" appears to be incorrect in that it was actually sent in 2009 on January 15.

2) A Field Alert report was not filed within three days for Iron Dextran 200 mg, lot 7020186, released to market 3/21/07, which contained particulate matter. The OOS was discovered on 3/11/08. The form used to report this Field Alert to FDA reads "Date Report Received 3/21/08" and it was not reported to FDA until 3/26/08. This 2/21/08 date would have met the three business day requirement, however no justification could be provided for the use of this date.

3) A Field Alert report was not filed within three days for Gentamicin Sulfate injection 100 mg/mL, lot 7030475 released to market 4/12/07, and 7081139 released to market 8/30/07, with the amounts of (b) (4) ingredients in the formulation transposed. It is unknown when this was discovered, but it was reported to FDA on 2/5/09. This incorrect formula with ingredients transposed had been used since the product was brought into the facility in June of 2001.

4) A Field Alert report was not filed within three days for Levothyroxine Sodium Tablets 0.2 mg, 0.5 mg, and 0.8 mg per tablet. The firm was aware of the problem as they had received (b) (4) complaints between 12/18/07 and 8/18/08. The filed alert was not reported to FDA until August 20, 2008. The date listed on this form reads "Date Report Received" was August 19, 2008.

5) A Field Alert report was not filed within three days for Levothyroxine Sodium tablets 0.2 mg, 0.5 mg, and 0.8 mg per tablet. A filed alert was reported to FDA March 31, 2009 during the inspection for lot 7030466 0.5 mg, released to market 9/5/2007. This Field Alert failed to include additional lots of tablets which the FDA uncovered during the inspection which had defects including various unidentified spots, and "fingernail" defects. See observation 3c for details.

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C) A production employee failed to follow procedure (b) (4), "Batch Formulation Procedures". Step 1 e requires the employee to rinse a hose for (b) (4) seconds before use. An Employee in the formulation room was observed to drop a clean hose on the wet floor drain and then gave it a quick squirt with hot WFI before connecting it to the tank and transferring (b) (4) lot (b) (4), not yet released to market, to another tank. This quick squirt appeared to be less than (b) (seconds. Additionally, the production employee had been trained on this procedure in December of 2008.

D) SOP "Airflow Testing", (b) (4) was not followed in that airflow testing ("smoke studies"), completed on 9/24/08 for line (b) (4) do not represent dynamic conditions. The procedure requires the study be conducted under dynamic conditions, yet personnel involved in routine manufacture of sterile products in the aseptic core were absent from the airflow studies. Additionally, the addition of stoppers and line manipulations were not included in this smoke study.

FAILURE TO FOLLOW PROCEDURES IS A REPEAT DEFICIENCY FROM THE PREVIOUS INSPECTION DATED 1/7-24/08

OBSERVATION 6

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,

Annual product reviews to be examined visually by the firm are not performed.
For example, Butorphanol 10mg/mL, Injection (USP) and Ketamine HCL Injection (USP) were not reviewed in 2007 and 2008.

Additionally, Annual Product Review procedure (Annual Product Reserve Sample Inspection (b) (4)) fails to specify how to conduct the visual exam. The Employee "DW" conducting the following exams does not have documented training to conduct the exam.

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2007:

- Epinephrine (product 600085)
- Vitamin C (product 600010)
- Amino Acid (product 500003)
- Sulfa 12.5% Oral Solution (Product: 500014)
- Ivermectin (product 500018)
- Dextrose (product 600001)
- Lactated Ringers (product 600012)

2008:

- Gonadorelin (product 600034)
- Epinephrine (product 600085)
- Sterile Water 100 cc (product 600009)
- Dinoprost (product 600092)
- Chlorhexiderm Shampoo 4% (product 500042)
- Flunixin (product 60052)

The above products and lots were initially reviewed by "DW" and subsequently reviewed during the inspection on 3/10/09 and were found to have particulates. Specifically,

- **Vitamin C, Lot:** 6071182 released to market 9/12/06, 6122001 released to market 2/2/07
- **Gonadorelin, Lot:** 7020268, 7020202, 7030371, 7030372, 7030488, 7040635, 7040554, 7040555, 7030492, 7050710, 7060838, 7050707, 7040644, 7030370, 7081092, 7060840, 7070966, 7070967, 7081094, 7081093, 7050708, 7060839, 7050709

  These batches were all released to market between 3/6/07 and 11/28/07.

- **Epinephrine Inj 30cc, Lot:** 7060857 released to market 11/26/07

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OBSERVATION 7

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

Procedure (b) (4) "Product Quality Complaint Investigations" was not followed. The complaint investigation into complaint 08-114, received 6/10/08 for crumbling Levothyroxine 0.5 mg tablets, lot 7101397 released to market 11/30/07, failed to extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. Five other complaints were received on other lots of the same product for crumbling tablets. Complaint 08-114 was the second complaint for lot 7101397, but no further investigation was made until at least (b) (4) more complaints were received. As of 3/23/09, (b) (4) complaints were received on over (b) (4) different lots.

OBSERVATION 8

Employees are not given training in the particular operations they perform as part of their function and written procedures required by current good manufacturing practice regulations.

Specifically,

A) Investigation and Reporting of Incidents and Deviations: Specifically, the firm conducted training of procedure (b) (4), "Investigation and Reporting of Incidents and Deviations" on 5/29/08. Despite evidence of documented training on this date, the firm failed to follow major portions of conducting investigations for DR # (b) (4) (completed on 2/9/09) and DR# (b) (4) (completed on 11/24/08). Please refer to Observation 3 for examples of deviations noted in investigations conducted by firm employees despite this training.

B) The training conducted by the firm on 10/14/08, regarding General Validation Policy, (b) (4), was ineffective as evidenced by the lack of execution of this procedure in the areas of Process Validation for applicable drug products. See Observation 4 for details of deficiencies noted. Additionally, this

procedure was not followed for the necessary execution of documenting qualification of manufacturing equipment.

LABORATORY:

C) (b) (4) out of the (b) (4) Employees who performed the Annual Product Reserve inspection for 2008 were not trained, as required by (b) (4) (Annual Product Reserve Sample Inspection) prior to February 2009. Untrained personnel have been doing annual product reserve inspections on products such as Lidocaine, Thiamine and Vitamin C since 2005. FDA inspectors did a brief inspection of the same reserve samples 3-2-09 and found (b) (4) lots of Thiamine Hydrochloride, (b) (4) lot of Lidocaine Hydrochloride, and (b) (4) lots of Phenylbutazone with particles in the samples.

D) Chemist "MC" operating in the firm has training records showing that (b) (4) procedures were "COVERED", yet no person conducting or overseeing the training signed the form as acceptable. Also, there is no date on the training form of when this training occurred.

In "December, 2007", the employee MC "COVERED" (b) (4) Procedures and the training document was never signed by the person conducting or overseeing the training.

In "October, 2007", this employee "COVERED" (b) (4) procedures, but the training document was never signed by the person conducting or overseeing the training.

EMPLOYEES PERFORMING GMP FUNCTIONS, WHO LACK ADEQUATE TRAINING, IS A REPEAT DEFICIENCY FROM THE PREVIOUS INSPECTION, DATED 1/7-24/08.

OBSERVATION 9

The reserve sample of drug product does not consist of at least twice the quantity necessary to perform all the required tests of drug product.

Specifically,

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ronald A. Schultz, Sr. Vice President of Quality Management, North America

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Saint Joseph, MO 64503	Drug Manufacturer

The firm collects (b) (4) retain samples when 6 units are necessary to fulfill all the required tests. The firm currently retains (b) (4) units from the following products:

SVP:

Lidocaine 2% (100 mL and 250 mL)
Vitamin C (100 mL)
Vitamin B12, 1000 mcg (100 mL and 250 mL)
Vitamin B12, 3000 mcg (100 mL and 250 mL)
Thiamine HCL 200 mg (100 mL and 250 mL)
(b) (4) ((b) (4) mL)
Xylazine Injection 100 mg/mL (50 mL)
Dexamethasone Injection, 2 mg/mL (100 mL)
Ketamine HCL, 100 mg/mL (10 mL)
Iron Dextran, 100 mg/mL (100 mL)
Gentamicin 100 mg/mL (100 mL and 250 mL)
Phenylbutazone Injectable 20% (100 mL)
Vitamin K1 Injection, 10 mg/mL (100 mL)
Oxytetracycline 200 mg/mL (100 mL, 250 mL, 500 mL)
Flunixin Meglumine (100 mL)
Treplenennamine HCL (250 mL and 500 mL)

LVP:

Dextrose 50% (500 mL)
Calcium Gluconate 23% (500 mL)
Cal Phos #2 w/ Potassium (500 mL)
Cal Phos #2 (500 mL)
Sterile Saline (250 mL, 500 mL and 1000mL)
Sodium Iodide (250 mL)
Dexolyte (500 mL and 1000 mL)
Hyper Saline Solution 7.2% (1000 mL)

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The above listed items may not be all inclusive.

THE FOLLOWING OBSERVATIONS RELATE TO THE LABORATORY SYSTEM

OBSERVATION 10

Determinations of conformance to appropriate written specifications for acceptance are not made for drug products.

Specifically,

No particulate matter testing was ever conducted as required by the USP 31 for Epinephrine and Xylazine 100 mg injection and thirteen intravenous products. There are (b) (4) lots of Epinephrine and (b) (4) lots of Xylazine 100 mg injection on the market which have not been tested for particulates. There are at least (b) (4) other lots of intravenous products on the market that have never had particulate testing. The Vice President of Quality Management stated they have never conducted the particulate matter test for injectable products including Epinephrine and Xylazine.

OBSERVATION 11

The written stability program for drug products does not include specific test methods.

Specifically, the HPLC assay methods for the following sterile products have not been shown to be stability indicating. Also, impurities are not evaluated during stability studies. This list may not be all inclusive.

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Product	Manufacture Date Range	Lots on Market
Atropine Sulfate Injection	(b) (4) - (b) (4)	(b) (4)
Epinephrine Injection	(b) (4) - (b) (4)	(b) (4)
Lidocaine 2%	(b) (4) - (b) (4)	(b) (4)
Mannitol Injection	(b) (4) - (b) (4)	(b) (4)
Thiamine HCl	(b) (4) - (b) (4)	(b) (4)

OBSERVATION 12

Deviations from written specifications are not justified.

Specifically, the appearance specification for Praziquantel injection finished product and stability analysis does not conform to the approved specification. There is no justification for the change in specification and change control documentation does not include changes to the specification in all cases. As of February 1, 2006, the approved specification is "clear, colorless to tinted". The history of the specification is as follows:

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Stage of Testing	Appearance Specification	Date of Change
Finished Product Release	Clear, colorless to slightly yellow to pink solution	3/20/2006
	Clear, colorless to tinted liquid	12/20/2007
Stability Testing	Clear, colorless to pale yellow to pink solution	6/12/2006
	Clear, colorless to tinted liquid	10/17/2007
	Clear, colorless to pale yellow to pink solution	9/30/2008
	Clear, colorless to tinted liquid	11/12/2008

OBSERVATION 13

The in-process control procedures were deficient in that it did not include an examination of tablet and capsule weight variation.

Specifically, weight variation for tablet and capsule products including Levothyroxine Tablets, Praziquantel tablets 34 mg, Clindamycin Capsules 25mg and 300 mg, and Pheylbutazone tablets 100 mg is not being performed on individual tablets as required by in process control procedure. Instead, (b) (4) tablets are weighed and the average of those (b) (4) tablets is reported. Individual tablet weights are not determined. On 3/26/09, (b) (4) tablets from Levothyroxine 0.5 mg tablets lot # 7030466, released to market 9/5/07, were found with "fingernails" or "capping" defects. At FDA's request, these tablets were weighed individually and (b) (4) of the (b) (4) tablets were above the specified acceptable weight range.

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This observation applies to every tablet and every capsule manufactured at the firm.

OBSERVATION 14

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, the quality unit determined stability failures of appearance (pink) for praziquantel injection occurred on 11/24/03 for lot #2101219 and 9/16/04 for lot #4030302. Subsequent batches of product manufactured and released by QA in 2006 and 2007 had appearance results consistent with the confirmed failures. QA failed to investigate the results. This change in color has never been evaluated by the firm for potential impact on efficacy.

Additionally, a FDA field alert was not issued for these lots.

OBSERVATION 15

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established.

Specifically,

There is no validation data to support the use of the Lidocaine USP assay method for (b) (4) analysis. The USP method for Lidocaine does not include (b) (4) as an analyte for determination and was modified without appropriate validation studies. Lots of Lidocaine released using this method include but are not limited to: 9020104, 9020110, 8100738, 8100740, 8100748, 8100675, 8100709, 8100681 and 8100733.

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OBSERVATION 16

Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Review of the maintenance log for the (b) (4) System showed there was no maintenance documented for the system between 7-19-2001 (with the exception the (b) (4) was sent out 1-7-2004 for repair) to 3/09. (b) (4) in (b) (4) (b) (4) units/mL is analyzed on this instrument.

OBSERVATION 17

Adequate lighting is not provided in all areas.

Specifically,
The retention sample room (in the (b) (4) facility) does not contain enough light to allow for proper visual exams of reserve drug products.

The FDA investigational team required additional lighting (flashlights) to assist our visual exams when attempts to conduct exams under the current conditions. The light available in the reserve sample room was inadequate.

This room is used to store Reserve Samples of drug products manufactured in (b) (4), (b) (4) and (b) (4) area.

Also, the firm is utilizing this area to conduct visual examinations during investigations and annual review of products for visual signs of deterioration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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*** DATES OF INSPECTION:**
02/23/2009(Mon), 02/24/2009(Tue), 02/25/2009(Wed), 02/26/2009(Thu), 02/27/2009(Fri), 03/02/2009(Mon), 03/03/2009(Tue), 03/04/2009(Wed), 03/06/2009(Fri), 03/11/2009(Wed), 03/12/2009(Thu), 03/13/2009(Fri), 03/17/2009(Tue), 03/18/2009(Wed), 03/19/2009(Thu), 03/20/2009(Fri), 03/25/2009(Wed), 03/26/2009(Thu), 03/27/2009(Fri), 04/03/2009(Fri), 04/21/2009(Tue)

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