

Establishment Inspection Report

Ameridose, LLC
Framingham, MA 01702-6211

FEI: **3005881167**
EI Start: 09/17/2008
EI End: 09/18/2008

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SUMMARY

This FY 2008 limited inspection of Ameridose, LLC was conducted in follow up to the firm’s previous drug inspection and recent product recall. This inspection was conducted in accordance with Drug Manufacturing Inspections Compliance Program 7356.002 and FACTS 970608.

Ameridose was last inspected July 21 through August 6, 2008. A Form FDA 483 Inspectional Observations was issued for 1) testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release; 2) written procedures are lacking which describe in sufficient detail the identification, sampling, testing, approval, and rejection of components; 3) master production and control records are deficient in that they do not include a statement of theoretical yield and minimum, maximum, and yield percentages; 4) batch production and control records do not include results of the inspection of the packaging and labeling area before and after use for each batch of drug product produced; 5) batch production and control records are deficient in that they do not include a statement of the actual yield and percentage of theoretical yield; and 6) written production and process control procedures are not followed in the execution of production and process control functions. Mr. Conigliaro stated a written response to the Form FDA 483 was submitted on or about August 22nd.

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As part of the previous inspection FDA samples 366491 – Fentanyl (as Citrate) and 366492 – Oxytocin were collected and tested for sterility, potency and identity. Based on the results of sample 366491, on September 12th, the firm initiated a voluntary product recall for the potential product “potency may be higher than the labeled value”. Sample 366492 results are pending.

This inspection covered review of manufacturing worksheets, labeling, invoices and shipping records specific to samples 366491 and 366492 as well as follow up discussion specific to questions addressed during the previous inspection. A Form FDA 463a Affidavit was signed by Gregory A. Conigliaro, General Manager/Vice President. A Form FDA 483 was not issued and additional samples were not collected.

ADMINISTRATIVE DATA

Post inspectional correspondence should be addressed to Mr. Gregory A. Conigliaro, General Manager/Vice President at the referenced mailing address.

Inspected Firm: Ameridose, LLC
Corporate Location: 50 Fountain Street
Framingham, MA 01702-6211
Manufacture Location: 695 Waverly Street Framingham, MA
Framingham, MA 01702-6211
Phone: 508-656-2653
FAX: 508-820-0644
Mailing Address: 50 Fountain Street
Framingham, MA 01702-6211
Website: www.ameridose.com
Dates of Inspection: 9/17/2008, 9/18/2008
Days in Facility: 2
Participants: Michelle M. Noe, Investigator

On September 15th, FDA credentials were displayed and a completed Form FDA 482 Notice of Inspection was issued by FDA Investigator Madigan to Mr. Gregory A. Conigliaro. (*Attachment 1*)

This inspection was preannounced to Mr. Gregory A. Conigliaro, General Manager/Vice President on September 16th for he called the New England District Office questioning the whereabouts of Investigator Madigan. She had planned to return to the firm on September 16th; however, she was deployed for a U.S. Public Health Service mission.

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On September 17th, FDA credentials were displayed and a completed Form FDA 482 Notice of Inspection was issued by me to Mr. Gregory A. Conigliaro. (*Attachment 2*)

On September 18th, Mr. Gregory A. Conigliaro, General Manager/Vice President signed a Form FDA 463a Affidavit. (*Attachment 3*)

HISTORY

Ameridose, LLC is a private domestic limited liability company which organized on February 8, 2006 in the State of Massachusetts. Mr. Gregory A. Conigliaro and Mr. Barry J. Cadden are designated as Managers of the business. On July 13, 2006, the company opened operations at its present locations, 50 Fountain Street Framingham, MA and 695 Waverly Street Framingham, MA. Mr. Conigliaro stated the company has no subsidiaries or related businesses and no other locations.

Previous Inspection

Ameridose was last inspected July 21st through August 6, 2008. A Form FDA 483 Inspectional Observations was issued for 1) testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release; 2) written procedures are lacking which describe in sufficient detail the identification, sampling, testing, approval, and rejection of components; 3) master production and control records are deficient in that they do not include a statement of theoretical yield and minimum, maximum, and yield percentages; 4) batch production and control records do not include results of the inspection of the packaging and labeling area before and after use for each batch of drug product produced; 5) batch production and control records are deficient in that they do not include a statement of the actual yield and percentage of theoretical yield; and 6) written production and process control procedures are not followed in the execution of production and process control functions. Mr. Conigliaro stated a written response to the Form FDA 483 was submitted on or about August 22nd.

As part of the previous inspection, FDA sample 366491 – Fentanyl (as Citrate) and 366492 – Oxytocin was collected and tested for sterility, potency and identity. Based on the results of sample 366491, on September 12th, the firm initiated a voluntary product recall due to the potential that the product “potency may be higher than the labeled value”. Sample 366492 results are pending.

INTERSTATE COMMERCE

Based on the previous establishment report, Ameridose ships (b) (4) of its finished product outside the State of Massachusetts. According to the company website, Ameridose services all 50 states.

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Hospitals are the firm's primary customers. Purchase orders are received from a hospital pharmacist and/or purchase/buyer via facsimile or internet at <http://www.ameridose.com/Ameridose-Online-Ordering.html>. Documentation of interstate shipping records for samples 366491 and 366492 were collected. Finished product is shipped directly from Ameridose to its customers via (b) (4). Mr. Conigliaro stated (b) (4) is considered the firm's primary shipper and performs an estimated 95% of its deliveries.

JURISDICTION

Ameridose is a unit dose repackaging and sterile admixing services company. Based on the previous establishment report, Ameridose markets and distributes over 600 products including: seven (7) antibiotic classes; fifteen (15) Class II; one (1) Class III; two (2) Class IV; and many Class VI products. A product list was collected during the previous inspection. According to the company website, Ameridose offers the following products for sale to customers nationwide:

Sterile Admixing Services

Antibiotic Admixtures	Electrolyte Admixtures
PCA Admixtures	Operating Room Syringes
Epidural Admixtures	Sterile Repackaged Syringes
Labor & Delivery Admixtures	Miscellaneous Admixtures

Oral Syringe Repackaging Services

Schedule II Narcotics	Schedule IV Controlled Substances
Hydromorphone	Chloral Hydrate
Meperidine	Diazepam
Methadone	Lorazepam
Morphine	Midazolam
Oxycodone	Phenobarbital
Schedule III Combination Controlled Substances	Schedule V Combination Controlled Substances
Hydrocodone Bitartrate / Acetaminophen	Codeine / Guaifenesin
Hydrocodone Bitartrate / Ibuprofen	Codeine / Guaifenesin / Phenylephrine
Hydrocodone / Guaifenesin	Schedule VI (Legend Drugs) & OTC
Hydrocodone / Guaifenesin / Phenylephrine	Vancomycin
Tylenol with Codeine	Others upon Request

Mr. Conigliaro reported 99% of the firm's business is not patient specific and the remaining 1% is patient specific (i.e. dialysis patients). Mr. Conigliaro stated that, except for dialysis patient purchase orders, Ameridose does not receive patient names on customer orders, only the total quantity requested. Mr. Conigliaro noted Ameridose does not service home delivery. Ameridose is responsible for the labeling of finished product. Examples of product labels for Fentanyl and

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Oxytocin were collected. Refer to the section of this report entitled, “Manufacturing/Design Operations”.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

A photocopy of the Ameridose organizational chart was collected and attached as *Exhibit 1*.

Gregory A. Conigliaro

Vice President/General Manager

Mr. Conigliaro identified himself as the most responsible individual. He stated he is Vice President/General Manager and has been since the company was founded in February 2006, noting there is no designated President. He explained he has the authority to sign checks, take loans and hire personnel. He stated he has a background in engineering. Mr. Conigliaro explained he does not report to a specific individual but is accountable to the Board of Members. There are four individuals which make up the Board of Members. Mr. Barry Cadden is designated as one of the four Members. Mr. Conigliaro noted the Board of Members are not involved in the day-to-day activities of the business; however, Mr. Cadden has the authority to act as his designee (i.e. sign checks). Mr. Conigliaro chose not to disclose the other Members. Note: Mr. Cadden is Mr. Conigliaro’s brother-in-law. He is President/Director of New England Compounding Pharmacy, Inc. located at 697 Waverly Street Framingham, MA. Mr. Conigliaro stated Mr. Cadden owns the patient specific compounding pharmacy and that Mr. Cadden’s “company is not an FDA facility, it is purely a pharmacy located in the State of Massachusetts.”

Mr. Conigliaro confirmed that he is most responsible for all operations of Ameridose and as such, has full knowledge of the day-to-day operations including regulatory, manufacturing, human resources, and financials. He has knowledge of, and can identify, records associated with the receipt, storage, manufacture, label, and shipment of inventories by the firm. (*Attachment 3*) Mr. Conigliaro has several direct reports at the management level, i.e. Ms. Sophia Pasedis, Vice President Regulatory Affairs, PIC, responsible for pharmacy oversight (b)(4) pharmacists) and FDA regulations. Mr. Conigliaro stated that Ameridose is “an FDA facility, naturally.”

Melanie Cerullo

Director of Quality

Ms. Cerullo reported she is responsible for the firm’s overall quality system including, documentation, training, change control, deviations, complaints and routine quality review. Ms. Cerullo stated she is responsible for release of in-process and finished product. Ms. Cerullo has been employed by Ameridose since October 1, 2007 and reports to Mr. Conigliaro.

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MANUFACTURING/DESIGN OPERATIONSORDER RECEIPT / PROCESSING

Mr. Conigliaro stated all purchase orders are received from a hospital pharmacist and/or purchase/buyer via facsimile or internet at <http://www.ameridose.com/Ameridose-Online-Ordering.html>. He noted Ameridose does not service home delivery and does not work with a wholesale supply chain. SOPs No. 2.040 version 1.0 entitled, "Order Process" and 2.0 (draft) entitled, "Order Processing and Generation of Formulary Worksheet" were reviewed.

Mr. Conigliaro reported 99% of the firm's business is not patient specific and the remaining 1% is patient specific (i.e. dialysis patients). He stated that, except for dialysis patient purchase orders, Ameridose does not receive patient names on customer orders, only the total quantity requested. To fill orders product is either pulled from the firm's existing inventory or a new lot is manufactured.

Ms. Cerullo stated Ameridose uses (b) (4) Software, generic pharmacy software, which randomly assigns a lot number (in-process and finished product) and generates an order label. This order label is not used on the product. Refer to *Exhibit 7, pages 4, 6, 8, 10, 12* & *Exhibit 12, pages 2, 4, 7, 9, 18, 12, 15, 21, 24, 26, 28*. It is only affixed to the purchase order form. This label includes an Rx number. This Rx number is not used by Ameridose, for the firm relies on the customer order number and lot number to track product. Mr. Conigliaro stated Ameridose uses (b) (4) to generate its packing slips and invoices. Finished product is shipped directly from Ameridose to its customers via (b) (4) labels are affixed to the invoices. Refer to *Exhibit 7, pages 5, 7, 9, 11, 13* & *Exhibit 12, pages 3, 5, 8, 11, 13, 16, 19, 22, 25, 27, 29*. (b) (4) is considered the firm's primary shipper and performs an estimated 95% of its deliveries.

FENTANYL CITRATE 0.9% NACL 10mcg/mL - Lot 07302008@4RAW MATERIAL

On or about July 1, 2008 Ameridose received a shipment consisting of (b) (4) units of Fentanyl Citrate Powder-USP (non-sterile active) - Lot (b) (4) from (b) (4) via (b) (4) (no tracking number available). A photocopy of raw material shipment/receipt and certificate of analysis was collected and attached as *Exhibit 2*.

Ms. Cerullo stated the firm does not perform identity testing on incoming raw material for it relies on the certificate of analysis. She confirmed that raw material testing of incoming product is not included in the firm's current SOPs. Ms. Cerullo did note that some raw materials have been identity tested but it is not the firm's normal practice to do so and that these raw materials were tested solely for a specific reason, i.e. development. She explained that Ms. Pasedis was the best person to ask regarding this question; however, she was not available.

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CONCENTRATE

A portion of Lot (b) (4) was used on July 2, 2008 to manufacture (b) (4) (20mL) syringes and (b) (4) (50mL) syringes of Fentanyl Concentrate in H₂O 10mg/mL, Lot 07012008@96. A photocopy of the manufacture worksheet was collected and attached as *Exhibit 3*. The firm does not perform identity testing on the concentrate.

STOCK SOLUTION

A portion of Lot 07012008@96 was used on July 9, 2008 and July 15, 2008 to manufacture Fentanyl (as Citrate) in SWFI 50mcg/mL 4000mL Stock Solution Lot 07082008@109 and Lot 07142008@109, respectively.

Samples of Fentanyl Stock Solution (1 syringe) were sent to (b) (4) to test potency/purity, endotoxin and sterility. Stock Solution were held in quarantine until receipt of results (CoA dated July 28, 2008 and July 30, 2008), and subsequently released by Director of Quality and/or Director of Pharmacy and/or Narcotics Pharmacist.

A photocopy of the manufacture worksheets and certificate of analyses/testing was collected and attached as *Exhibit 4 & 5*.

FINISHED PRODUCT / LABELING

A portion of Lot 07082008@109 and Lot 07142008@109 was used on or about August 1, 2008 to manufacture (b) (4) finished product units: Fentanyl Citrate in 0.9% NACL 10mg/mL 100mL Injectible bag, Lot 07302008@4.

A sample of finished product (1 syringe) pulled from multiple finished product injectable bags was sent to (b) (4) to test (b) (4) sterility. The only test performed on all finished products is sterility. It is the firm's normal practice to release finished product prior to receipt of results. Lot 07302008@4 was released by a Staff Pharmacist prior to receipt of sterility results (CoA dated August 19, 2008), upon final inspection of the lot.

A photocopy of the manufacture worksheets and certificate of analysis/testing was collected and attached as *Exhibit 6*.

For Fentanyl, Ameridose affixes a white label with black lettering on (b) (4) injectable bags. The Ameridose label covers the (b) (4) blue lettering imprinted on the bag, however, a portion of the lettering remains visible which includes but is not limited to, "***Lot xxx Exp xxx 100 mL NDC (b) (4) 0.9% SODIUM CHLORIDE Injection, USP***". In addition to the (b) (4) lettering,

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the finished product is labeled in part, “***Preservative Free 10mcg/mL FENTanyl (as Citrate) in 0.9% Sodium Chloride Total Fentanyl Dose 1,000mcg/100mL Content volume 100mL in 100mL Injectable Bag Exp: xx/xx/xxxx [month/day/year] Lot: xxxxxxxx@xxx Rx Only AMERIDOSE Framingham, MA 01702...CII Store at Room Temperature Single-Dose Bag [BARCODE] NDC: 2420025104***”. Each product is placed in an Ameridose over-wrap tamperproof bag. There is no specific labeling on the bag.

A photocopy of an example of the finished product label was collected and attached as *Exhibit 6a*.

FINISHED PRODUCT SHIPMENT

The following customers received shipment of Fentanyl Citrate in 0.9% NACL 10mcg/mL Injectable bag, *Lot 07302008@4* via (b) (4). A photocopy of documentation of distributed product including a master customer list for *Lot 07302008@4*, purchase orders, and invoices with (b) (4) tracking numbers were collected and attached as *Exhibit 7*.

Order No.	Customer	Address	Qty Dispensed	Date Dispensed	(b) (4) Tracking No.
3574	(b) (4)	(b) (4)	(b) (4) bags	7/31/08	(b) (4)
3548	(b) (4)	(b) (4)	(b) (4) bags	7/31/08	(b) (4)
3710	(b) (4)	(b) (4)	(b) (4) bags	8/2/08	(b) (4)
3807	(b) (4)	(b) (4)	(b) (4) bags	8/4/08	(b) (4)

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4086	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
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Oxytocin added to 0.9% NACL 30 units/500mL injectable bag, Lot 08022008@54**RAW MATERIAL**

On or about March 14, 2008 my firm received a shipment consisting of one (b) (4) of Oxytocin, USP (non-sterile active powder) Lot (b) (4) from (b) (4). (b) (4) via (b) (4) (no tracking number available). A photocopy of raw material shipment/receipt and certificate of analysis was collected and attached as *Exhibit 8*.

As previously noted, Ms. Cerullo stated the firm does not perform identity testing on incoming raw material for it relies on the certificate of analysis. She confirmed that raw material testing of incoming product is not included in the firm's current SOPs. Ms. Cerullo did note that some raw materials have been identity tested but it is not the firm's normal practice to do so and that these raw materials were tested solely for a specific reason, i.e. development. She explained that Ms. Pasedis was the best person to ask regarding this question; however, she was not available.

STOCK SOLUTION

A portion of Lot (b) (4) was used on July 11, 2008 to manufacture (b) (4) (4000mL) bags of Oxytocin in SWFI 10 units/mL 4000mL Stock Solution, Lot 07102008@83.

A samples of Oxytocin Stock Solution (1 syringe) was sent to (b) (4) to test potency/purity, endotoxin and sterility. Stock Solution was held in quarantine until receipt of results (CoA dated July 28, 2008), and subsequently released by Director of Quality and/or Director of Pharmacy and/or Narcotics/Vault Pharmacist.

A photocopy of the manufacture worksheet and certificate of analysis/testing was collected and attached as Exhibit 9.

FINISHED PRODUCT / LABELING

A portion of Lot 07102008@83 was used on August 4, 2008 to manufacture (b) (4) finished product units: Oxytocin added to 0.9% NACL 30 units/500mL injectable bag, Lot 08022008@54.

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A sample of finished product (1 syringe) pulled from multiple finished product injectable bags was sent to (b) (4) S to test (b) day sterility. The only test performed on all finished products is sterility. It is the firm's normal practice to release finished product prior to receipt of results. Lot 08022008@54 was released by a Staff Pharmacist prior to receipt of sterility results (CoA dated August 20, 2008), upon final inspection of the lot.

A photocopy of the manufacture worksheet and certificate of analysis/testing was collected and attached as *Exhibit 10*.

For Oxytocin, Ameridose affixes a green label with black lettering on (b) (4) injectable bags. The Ameridose label covers the (b) (4) blue lettering imprinted on the bag, however, a portion of the lettering remains visible which includes but is not limited to, "****Lot xxx Exp xxx 500 mL NDC (b) (4) 0.9% SODIUM CHLORIDE Injection, USP****". In addition to the (b) (4) lettering, the finished product is labeled in part, "****OxyTOCIN 30 Units added to 500 mL 0.9% Sodium Chloride Inj. Store at Room Temperature, Protect from Freezing. Exp: xx/xx/xxxx [month/day/year] Rx Only AMERIDOSE Framingham, MA 01702 Single-Dose Bag [Barcode] NDC: 2420020613****". Each product is placed in an Ameridose over-wrap tamperproof bag. There is no specific labeling on the bag.

FINISHED PRODUCT SHIPMENT

The following customers received a shipment of Oxytocin added to 0.9% NACL 30 units/500mL Injectable bags, Lot 08022008@54 via (b) (4). A photocopy of documentation of distributed product including a master customer list for Lot 08022008@54, purchase orders, and invoices with (b) (4) tracking numbers were collected and attached as *Exhibit 12*.

Order No.	Customer	Address	Qty Dispensed	Date Dispensed	(b) (4) Tracking No.
4191	(b) (4) (b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
4197	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
4134	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
4094	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)

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					(b) (4)
4160	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
4078	(b) (4)	(b) (4)	(b) (4) bags	8/6/08	(b) (4)
4056	(b) (4)	(b) (4)	(b) (4) bags	8/5/08	(b) (4)
4028	(b) (4)	(b) (4)	(b) (4) bags	8/5/08	(b) (4)
4045	(b) (4)	(b) (4)	(b) (4) bags	8/5/08	(b) (4)
3950	(b) (4)	(b) (4)	(b) (4) bags	8/5/08	(b) (4)
3952	(b) (4)	(b) (4)	(b) (4) bags	8/5/08	(b) (4)

MANUFACTURING CODES

Ms. Cerullo stated Ameridose uses (b) (4) Software, generic pharmacy software, which randomly assigns lot numbers. The firm's lot numbers are not specific to a date or batch sequence, each batch (in-process and finished product) has a unique lot number.

DEVIATION

A photocopy of Deviation No. D08118 was collected and attached as *Exhibit 13*. This deviation was noted during finished product preparation of Fentanyl/Ropivacaine in 0.9% NaCL 1 mcg/0.2% 100mL Injectable Bag, Lot 07162008@166. The pharmacy technician inadvertently spiked the Fentanyl Stock Solution bag with the tubing set that had been used in the Ropivacaine bag. The pharmacist was notified immediately and the Fentanyl Stock Solution that was contaminated was

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scrapped to waste. There was no product impact reported. The root cause of the deviation was human error.

STERILITY POSITIVE

Ms. Cerullo stated the firm has received one positive sterility result. A photocopy of Out-of-Specification No. OOS08052 was collected and attached as *Exhibit 14*. This positive sterility result for Day (b) (June 16, 2008) Fentanyl 50 mcg/mL, Lot 05292008@74 was investigated and concluded to be due to an error on the part of (b) (4).

GENERAL DISCUSSION WITH MANAGEMENT

Ms. Cerullo reported finished product shelf life ranges from 14 to 90 days, based on the product. Fentanyl Citrate in 0.9% NACL 10mcg/mL Injectable bags are labeled with a 45 day shelf life. Oxytocin added to 0.9% NACL 30 units/500mL Injectable bags are labeled with a 90 day shelf life.

Ms. Cerullo confirmed that the firm has not performed a sterilization validation study. She stated the firm tests the stock solution for sterility and performs integrity testing on the filter used after preparing the lot. Mr. Cerullo and Mr. Conigliaro explained that “every time the product is made the stock solution is validated, because it is tested for sterility”. They noted that if the firm was to validate the process this is what it would do.

Ms. Cerullo presented a Bag Overfill Study Summary which was performed to evaluate the overfill associated with 100 mL (b) (4) Normal Saline bags. A photocopy of the Summary was collected and attached as *Exhibit 15*. Ms. Cerullo explained this study was used to determine the volume of (b) (4). This evacuation and addition is outlined in the manufacture worksheet for finished product Fentanyl Citrate in 0.9% NACL 10mg/mL 100mL Injectable bag, Lot 07302008@4. Refer to *Exhibit 6, Page 1*.

Mr. Conigliaro stated a written response to the Form FDA 483 was submitted on or about August 22nd. He noted that as part of the response the firm has committed to implement identity testing of its finished products. Ms. Cerullo stated SOP No. 6.021 version 1.0 entitled, “QA Sample Process and Library” was effective at the time of the previous inspection. She explained that the firm has revised SOP No. 6.021 to version 2.0 and is in the process of training employees on the new version. A photocopy of SOP No. 6.021 version 1.0 and 2.0 was collected and attached as *Exhibit 16a-b*.

A Form FDA 463a Affidavit was signed by Gregory A. Conigliaro, General Manager/Vice President. A Form FDA 483 was not issued and additional samples were not collected.

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ATTACHMENTS

Form FDA 482 Notice of Inspection dated 9/15/08 issued to Gregory A. Conigliaro, General Manager/Vice President	1 pg
Form FDA 482 Notice of Inspection dated 9/17/08 issued to Gregory A. Conigliaro, General Manager/Vice President	1 pg
Form FDA 463a Affidavit dated 9/18/08 issued to and signed by Gregory A. Conigliaro, General Manager/Vice President	5 pgs

EXHIBITS COLLECTED

1	Ameridose Organizational Chart	1 pg
2	Raw Material: Fentanyl Citrate Powder- USP - (b) (4)	5 pgs
3	Concentrate: Fentanyl Concentrate in H ₂ O 10mg/mL, Lot 07012008@96	6 pgs
4	Stock Solution: Fentanyl (as Citrate) in SWFI 50mcg/mL 4000mL Stock Solution Lot 07082008@109	11 pgs
5	Stock Solution: Fentanyl (as Citrate) in SWFI 50mcg/mL 4000mL Stock Solution Lot 07142008@109	14 pgs
6	Finished Product: Fentanyl Citrate in 0.9% NACL 10mg/mL 100mL Injectable bag, Lot 07302008@4	6 pgs
6a	Label Example: Fentanyl Citrate in 0.9% NACL 10mg/mL 100mL Injectable bag	2 pgs
7	Orders/Shipment: Fentanyl Citrate in 0.9% NACL 10mcg/mL Lot 07302008@4	13 pgs
8	Raw Material: Oxytocin, USP (non-sterile active powder) Lot (b) (4)	4 pgs
9	Stock Solution: Oxytocin in SWFI 10 units/mL 4000mL Stock Solution, Lot 07102008@83	12 pgs
10	Finished Product: Oxytocin added to 0.9% NACL 30 units/500mL injectable bag, Lot 08022008@54	6 pgs
11	Label Example: Oxytocin added to 0.9% NACL 30 units/500mL injectable bag	1 pg
12	Orders/Shipment: Oxytocin added to 0.9% NACL 30 units/500mL injectable bag, Lot 08022008@54	29 pg
13	Deviation No. D08118	3 pgs
14	Out-of-Specification No. OOS08052	14 pgs
15	Bag Overfill Study Summary 100 mL (b) (4) NS Bag	4 pgs
16a	SOP No. 6.021 version 1.0 entitled, "QA Sample Process and Library"	4 pgs
16b	SOP No. 6.021 version 2.0 entitled, "QA Sample Process and Library"	9 pgs



Michelle M. Noe, Investigator